

STANDARDISED EXTRACTS: USE, EXPERIENCES AND OPINIONS OF UK REGISTERED WESTERN HERBALISTS

by

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ABSTRACT

Traditionally Western Herbal Medicine (WHM) uses ‘whole plant extracts’ (WPEs), typically presented as liquid extracts, teas and powders. There is no formal measurement of any identified plant chemicals in WPEs. In contrast, preparations called ‘standardised extracts’ offer a guaranteed minimum content of specified plant constituents that have been identified in modern research studies. A limited number of these standardised extract preparations are in the form of ‘highly standardised extracts’ (HSEs), largely presented as tablets. They offer a much higher dose of identified ‘active constituent/s’ than is present in the WPE and are the focus of this study. This study uses a Grounded Theory (GT) with Mixed Methods Research (MMR) approach to investigate the use of these alternative herbal preparations (WPE vs HSE). It investigates how registered herbalists have come to use HSEs and their attitudes towards them, with a view to informing the debate and the wider interested community.

Findings indicate that there is limited but clear use of single HSEs by a large minority of participating respondents, with use influenced mainly by the growing body of research, historical influence of other herbalists and clinical evidence of ‘strength’. Other facilitating influences on HSE use were research-skills training which may have encouraged widespread open-mindedness, reduced historical controversy and lack of strong feelings against HSE. The major identified limiting factor in HSE use was the strong emphasis on the ‘natural’ WPE, with a ‘split’ in open-mindedness towards HSE. All herbalists reported use of herbal research, used for largely non-clinical reasons. Only limited evidence was identified of clinical ‘integration’ of research with practice by HSE users. Greater integration was suggested in a small minority of respondents which better reflects WHM practice in non-UK countries. Finally, it is acknowledged that response bias limits the strength of conclusions.

GLOSSARY OF CENTRAL TERMS

Whole plant extract (WPE) – an herbal preparation for which the content of plant constituents is not formally measured and typically reflects amounts of varying constituents as found in the whole plant.

Standardised extract – a general term for an herbal preparation that measures and guarantees a minimum stated percentage of a plant constituent or group of constituents. The relative content of constituents may be similar to a WPE or a HSE depending on the preparation.

Highly standardised extract (HSE) – an herbal preparation that contains a very much higher percentage content of an active plant constituent than occurs naturally in the whole plant.

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LIST OF ABBREVIATIONS

HSE	Highly standardised extract
WPE	Whole plant extract
WHM	Western Herbal Medicine
TK	Traditional Knowledge
TCM	Traditional Chinese Medicine
CAM	Complementary and Alternative Medicine
EBM	Evidence based medicine
RCT	Randomised control trial
PA	Professional association
NIMH	National Institute of Medical Herbalists
CPP	College of Practitioners of Phytotherapy
AMH	Association of Master Herbalists
URHP	United Register of Herbal Practitioners
ANP	Association of Naturopathic Practitioners

Chapter 1: Introduction

This thesis investigates the practice of UK registered herbalists, hereafter referred to as 'herbalists', who employ Western herbal medicine (WHM) and are members of UK Professional Associations (PAs). They typically work as healthcare providers, largely in private individual settings, offering a service to patients who seek treatment. The specific aspect of WHM practice considered here is use of, and attitudes towards, certain preparations of medicinal herbs, referred to in this context as 'highly standardised extracts' and from here on 'HSEs'.

Introductory information below offers a description of WHM, including how it is reported in contemporary literature and an explanation of the range of herbal preparations used as medicine. A specific explanation is given of how HSEs differ from other preparations.

WHM is largely practised around the 'Western' world in Australia, Canada, New Zealand, the United Kingdom, the United States and Western Europe but as a practice it has long been only loosely defined (Niemeyer et al., 2013). It was somewhat distinguished in the 1990s from other herbal traditions present in the West, such as Traditional Chinese Medicine (TCM), Ayurvedic medicine or Tibetan medical systems, as using *'plants largely native to Europe, within a philosophical tradition arising from European thought'* (Nissen, 2010, p. 181; 2015) and was described simply in 2000 by the UK Parliamentary Select Committee as *'A system of medicine which uses various remedies derived from plants and plant extracts to treat disorders and maintain good health'* (UK Parliament, 2021b). The Medicines Act, 1968 (Legislation.gov.uk, 2021), which allowed for the legality of herbal practice did not offer any definition of WHM or herbal practitioners. Nissen (2015) described WHM as *'characterized by a person-centred approach to healthcare, where the patient rather than the disease is in focus...(and) reflected in a therapeutic approach that encompasses the individualized use of herbs'* (p. 166). Lin et al. (2009) defined a WHM practitioner as one who *'engages in extemporaneous compounding of herbs for therapeutic purposes for individuals under his or her care, and who has satisfied the core training requirements in herbal medicine principles, philosophy, and practice'* (p.22). These descriptions are somewhat limited and they do not offer any guidance on the type of herbal preparation used. Waddell (2016) stated that WHM *'does not convey as clear an identity as many other... (Complementary and Alternative Medicine)... practices'* (p. 2), still lacking satisfactory definition. Bone (2021) reported WHM being viewed by other Complementary and

Alternative Medicine (CAM)¹ practices as having '*no well defined philosophy and prescribing system*' (p. xi). However, a clear definition of WHM may not be practical. The herbalist community has been described as representing '*varied and diverse groups of practitioners*' (Niemeyer et al., 2013, p. 2), being '*inherently multi-disciplinarian and heterogeneous*' (Treasure, 2014, p18), and is also variably referred to as '*traditional Western herbalism, herbal or botanical medicine, medical herbalism and phytotherapy*' (Niemeyer et al., 2013. p. 2). These terms referring to WHM suggest particular origins of plant knowledge. The word 'traditional' above, and in the context of this thesis, refers to a form of WHM based on 'Traditional Knowledge' (TK). There is no fixed definition of TK but it generally relates to a 'whole plant' approach (Treasure, 2014). This relation of TK to the 'whole plant' is significant for this study which focuses on the nature of plant preparations. TK is experiential and has accumulated over time (Niemeyer et al., 2013). It can be described as herbal knowledge that has a long, coherent, well documented history of use as well as being passed on orally over generations (Gray et al., 2019)). TK includes approaches such as 'Physiomedicalism' and 'Eclecticism' (originating in America) with the central importance of the 'vital force' (Waddell, 2016). It exists as a central resource for herbalists, particularly given the relative lack of satisfactory definition of WHM suggested above. In contrast to TK, the term 'phytotherapy' implies the use or inclusion of knowledge that has originated from modern research studies. These studies largely focus research-based herbal preparations such as HSE that are scientifically produced to offer reliability of measurements. This reliance on more 'measured' products contrasts with TK and its association with the more variable 'whole plant'. No UK herbalists defined themselves as 'phytotherapists' in Nissen (2010), most preferring the term 'medical herbalist'. According to Nissen (2010, p. 166; 2011) these loose definitions mask a '*plurality of practices.....(that) range from science orientated to spiritually informed practices that may or may not include herbs and philosophies of non-European origin*'. WHM has also been described as a '*mass of tensions*' (Waddell, 2016, p. 1) that may '*almost def(y) definition*' (Jackson-Main, 2005, p. 89). One of these tensions, the use of HSEs, is the subject of this thesis. Findings here add to the limited understanding of practice within this poorly described profession.

The therapeutic use of herbs by herbalists who practice WHM in the UK is based on the prescription of herbal medicine, typically following an individual consultation with the patient, which informs a treatment plan (see National Institute of Medical Herbalists website, www.NIMH.org.uk, the largest professional association for herbalists in the UK). Herbal medicines used in this way are based on a specific part of the plant (for example the leaf, root,

¹ There is no universal definition of CAMs. Examples include: homeopathy, acupuncture, osteopathy, chiropractic, herbal medicines (NHS, 2021).

bark, flower or seed), or sometimes the whole plant, and are prepared in a variety of ways. Trade suppliers offer a wide range of herbal medicines to herbalists in the UK, and herbalists may also produce their own on a smaller scale. The British Herbal Medicine Association includes a section on its website (BHMA, 2021) called the Health Practitioners Suppliers Section. This lists approved suppliers to herbalists and aims to support quality and safety of herbs sold. Several, but not all major suppliers to UK herbalists are included, although other suppliers have their own standards with the aim of achieving the same². Categories of medicines typically available from such herbalist suppliers are exemplified from those listed in the 'products' section on the Herbs in a Bottle website (Herbs in a Bottle, 2021). This is a typical supplier to herbalists and included on the BHMA register (2021). The products list consists of tinctures and fluid extracts (in an alcohol solvent of varying strength depending on the solubility of certain plant constituents). There are also gycerites (herbs in a glycerine solvent), dried herbs (leaves often are used for making aqueous 'infusions' with hot water and roots or barks may be simmered for longer as a 'decoction') and powdered herbs. The most commonly prescribed formulation by herbalists is a combination of several liquid herbal extracts (Casey et al., 2007; Walker, 2006). These preparations typically involve little processing.

Some herbal preparations may be 'standardised'. Standardised herbal preparations are typically available as liquids, capsules or tablets and are prepared to guarantee a stated concentration of a measured constituent or constituents. These chemicals have been identified in the plant by scientific research, some, but not all of which have been classed as 'active' constituents that are proposed to be responsible for, or contribute to, the therapeutic benefits of the herb. For example St John's Wort tincture (*Hypericum perforatum*) is typically standardised to the content of hypericin (e.g. 0.4mg/ml in the Mediherb tincture (Balance healthcare, 2021b)) and Echinacea spp. tincture is standardised to content of alkylamides (1.5 mg/ml alkylamides in Mediherb Echinacea Premium (Balance Healthcare 2021a)). Original research-based identification of plant constituents often goes back many decades and sometimes over a century. For example a search of PubMed and Google Scholar has records of 'hypericin' as early as 1951. The aim of standardisation is to support claims of quality or efficacy of the herbal product. However this is not guaranteed in practice, for example Ruiz et al. (2016) found standardising marker compounds did not predict bioactivity. The difference between standardised and non-standardised herbal preparations is that non-standardised

² Examples of major herbalist suppliers are Panacea (<https://www.panaceahealthonline.com/>); Avicenna (<http://www.avicennaherbs.co.uk/>); Planta Medica (<https://www.plantamedica.co.uk/>), Herbs in a Bottle (<https://www.herbsinabottle.com/>), Herbal Apothecary (<https://herbalapothecaryuk.com/>).

preparations are prepared from the herb or part of the herb, with no measurement or guarantee of constituent content. Constituents are presented in concentrations reflecting the natural presence in the plant. However, since this is not overtly measured, there is inherent variation between plants and between preparations used. For example different growing conditions lead to altered constituent balance and individual solvents provide different solutions due to varying solubilities of constituents in those solvents (Ruiz et al., 2016). Trade suppliers available to herbalists in the UK, largely stock non-standardised products although they may also offer a limited selection of standardised herbal preparations, for example as stocked by Balance Healthcare (2021a;b) above.

Herbal preparations from herbalist suppliers are generally not available for purchase to the general public. This is because preparations that are considered 'medicine' (rather than 'food') must have a 'Traditional Herbal Registration' (THR) for over-the-counter (OTC) sale (Gov.UK., 2021). Herbalist suppliers do not generally sell such products as herbalists can legally prescribe un-licensed herbal medicines. Herbal practice focuses on the use of these un-licensed medicines from trade suppliers as described above. In contrast these registered products form part of the large and growing market in OTC herbal preparations (Ruiz et al., 2016). They offer a mix of licenced and unlicensed herbal products (the latter defined as 'food'), that are freely available in health food shops, pharmacies and from online supplement companies³. Unlike the stock offered by dedicated herbalists' suppliers some but not all of these products are standardised. Searching online for herbal remedies that constitute the OTC market suggests that the availability of standardised products are variable depending on the company viewed. For example the popular natural health company Holland & Barratt (2021) which markets itself to the general public offers only few standardised herbal products compared to non-standardised. In contrast Lamberts Healthcare (2021e) states on their website that they *'favour standardised extracts since the extraction and concentration procedures ensure that the herbal preparation is far more potent than those products based on powdered whole herb, where no attempt is made to concentrate or standardise the products'*. Lamberts Healthcare therefore considers standardised preparations to offer a guarantee of potency or 'strength'.

Now that a distinction has been made between standardised and non-standardised herbal preparations, it is important to clarify and carefully define the specific herbal preparations that

³ There are a wide range of manufacturing supplement companies offering HSE products to health practitioners through trade accounts and the general public, including: Lamberts healthcare (e.g. <https://www.lambertshealthcare.co.uk/trade/herbs/other-herbs/milk-thistle-3000mg/>); Biocare (e.g. <https://www.biocare.co.uk/microcellr-curcumin-turmeric-complex-60-caps>) ; Nutri Advanced (e.g. <https://www.nutriadvanced.co.uk/categories/by-range/turmeric.html>)

are the focus of this thesis. Amongst this range of standardised herbal extracts outlined above, are a limited range of preparations which offer a form of a herb that has been prepared to provide a very high concentration of an identified specific active constituent or group of constituents. This is far higher than would be found in the non-standardised preparations and also higher than other standardised extracts cited above. These 'highly standardised extracts', HSEs, guarantee a level of the active constituent/s at a much higher percentage than in the unprocessed plant product. There are a limited number of herbs freely available for OTC purchase in the form of these highly concentrated HSEs. Examples that are commonly found in contemporary WHM herbal texts (see Table 3.2, p. 36) are *Curcuma longa* (turmeric) rhizome, *Silybum marianum* (milk thistle) seed, *Ginkgo biloba* leaf and *Serenoa serrulata* (saw palmetto) berry. For example *C. longa* HSE preparation typically contain 95% of the active constituents called curcuminoids, compared to 3-4% in the whole dried powdered rhizome (Tayyem et al., 2006). By concentrating and guaranteeing a certain very high percentage of a specific plant compound/s found to have therapeutic benefit or proposed desirable bioactivity in research, companies may imply an increased efficacy of these HSE herbal preparations.

Unlike other herbal preparations, HSEs are only available in tablet or capsule form as they are presented as small, precisely measured doses of a highly concentrated powder. This contrasts with the individualised formulae containing several herbs of varying doses that are generally prescribed by herbalists. Such presentation is not suited to the HSE format which, once prepared, is not readily incorporated with other herbs or the dose changed. Development and sale of these specific HSE preparations has followed evidence from the increasingly large body of modern scientific research studies, carried out over the past several decades. The research that has supported the development of HSEs focuses on the concentrated active constituents or the HSEs themselves. There is less attention to preparations that reflect the percentage of those constituents as found in the unprocessed herb. There is little or no research on these specific 'HSE' herbs in this more 'natural' form such as the whole, unprocessed *C. longa* rhizome. This more natural form of plants in general are referred to here as the 'whole plant extracts' (WPEs) and represent herbal preparations other than HSEs. As discussed above this may include other less highly standardised preparations that are considered to contain percentages of measured constituents which are close to the natural presentation. They may also include OTC proprietary herbal products, for example those produced by Lamberts Healthcare Ltd. (2021e). However UK WHM practice is largely based on less processed preparations that are produced by herbalist suppliers, as discussed above. These proprietary preparations manufactured by supplement companies are not considered to be widely used by UK herbalists. In this study WPE preparations used by UK herbalists are therefore understood

as those connected with 'traditional WHM' based on TK rather than relying on evidence from modern research.

Having defined UK WHM as based on the use of little-processed WPEs, there is also some use of the HSEs. They are used not only by herbalists, but the wider community, largely via self-prescription. The market for OTC herbal products is huge and continually growing (Bitcon et al., 2016; Hexa Research, 2021). It has been predicted that the market for tablets and capsules will be particularly fast growing, due to convenience and easy dosing (Hexa Research, 2021). OTC HSE use will therefore be likely to continue to increase. There is an ongoing debate amongst many herbalists about the perceived differences between HSEs and WPEs. It is this aspect of herbal practice that this thesis focuses on, expanding on initial evidence for herbalists' widespread use of *C. longa* HSE that was found recently by the author (Sprung, 2016).

1.1 Outline of the thesis

The outline of the thesis is as follows. Having introduced the study in Chapter 1, Chapter 2 moves on to discuss why the issue of HSE is important in WHM. It relates to the challenges to traditional WHM practice brought by HSEs and research which has provided the impetus for HSE development. Since HSEs were developed following research findings, any consideration of attitudes must therefore also include those towards research and both are included in the study. The relationship between WHM and both research and HSE is first explained and reviewed. Evidence is drawn from all countries where WHM research is carried out but with a focus on UK practice where possible since this study is limited to UK herbalists. Following this, in Chapter 3, the major individual HSE herbs are considered separately, outlining available evidence from research and texts that may influence choice of preparation. Chapter 4 offers a brief summary, aims and justification of the study. Chapter 5 gives details of methodology and methods which followed a grounded theory approach with mixed methodology and was based on interviews and an online survey. There is a specific summary of how qualitative interview data informed the online survey. Chapter 6 presents results from both interviews and survey together in a narrative weaving approach. The discussion section, Chapter 7, considers how the results and existing literature paint a wider picture of herbal practice. This is followed by followed by strengths and limitations of the study. Finally the conclusion, Chapter 8, highlights important findings, considers implications of the study and offers suggestions for further research.

Chapter 2: HSE and modern research in WHM: Introduction and controversy

The issues of modern research and related 'highly standardised extract' (HSE) preparations are important in Western Herbal Medicine (WHM). They represent an aspect of practice that contrasts with the methods and materials of the 'Traditional Knowledge' (TK) approach. There is a lack of agreement within the herbal community about their use. There has been a long history of controversy in parts of the WHM community concerning both issues, now spanning decades. Indeed concerns around standardisation of herbs to specified constituents in general, discussed below, goes back over a century (Wahlberg, 2008). The investigation of herbal constituents was documented as early as the 19th Century (for example concerning atropine, found in *Atropa belladonna* (Reisinger, 1826)). The discussion below first outlines the development of HSEs from increasing modern research evidence over the last few decades. It then explains moves to modernise WHM through engagement with the increasing body of scientific plant research associated with the 'Evidence Based Medicine' (EBM) approach. This both reflects and contrasts with similar changes over the last century. The issue of the controversy surrounding HSE and modern research in parts of the WHM community is then considered. After this, subsequent changes in terms of how WHM is currently viewed in the wider world are outlined. A review is offered of how the WHM profession has adapted to this focus on research methods, in terms of integration of research and HSE into practice.

The review of evidence below, concerning these issues, also includes research on 'Complementary and Alternative Medicine' (CAM), of which WHM is a part. This is because research specifically on WHM is limited, particularly in the UK. However, WHM may be only one of several modalities considered in these research studies and conclusions are drawn with this in mind, although it is assumed that attitudes towards CAM may also be cautiously applied to WHM. The relative representation of WHM in CAM studies is variable. For example health professionals providing conventional medicine have been reported to focus more on other modalities than WHM (Posadzki, 2012) but studies of CAM concerning the general public have found the use of herbal medicine a comparatively more popular therapy (Ernst & White, 2000; Posadzki et al., 2013a;b). Popularity with the general public may be due to ease of access of OTC products and reflected in the huge OTC herbal market (Hexa Research, 2021). Also included in the review of the research is the profession of naturopaths who use WHM as part of their practice as well as a range of other healthcare modalities.

2.1 Development of HSEs from modern research

The use of these limited number of modern HSE preparations in WHM, specifically considered in this study, can be traced back to the rapid increase in medical research towards the end of

the 20th Century. This is shown graphically in PubMed timeline searches using medical terms⁴, coinciding with the introduction of EBM in the West. EBM was originally introduced as a research literacy movement in medical education (Wyer & da Sylva, 2015). It was further specified for use in healthcare settings and defined (through the Evidence-Based Medicine Working Group, 1992) as a way to achieve the '*integration of best research evidence with clinical expertise and patient values*' (Sackett et al., 2000, p. 1). At its core it is a concept that is synonymous with the clinical application of modern health research (Wyer & da Sylva, 2015) but there has been considerable controversy surrounding the practical application of EBM methods in conventional healthcare (Charlton, 2009; Goldenberg, 2006; Miles, 2009; Greenhalgh, 2020; Fernandez et al., 2015; Miles & Loughlin, 2006; Cohne & Hersh, 2004; Sur & Dahm, 2011). Reliance on 'gold-standard' randomised control trials (RCTs) are central to the EBM approach and involve application of the same treatment to subjects, compared to placebo; a positivist and epidemiological approach. Such a central focus has long been criticised (Car-Hill, 1995). Such RCT evidence generally eliminates issues of culture and context, practitioner experience, or questions about knowledge generation methods (Goldenberg, 2006). Goldenberg (2006, p.2622) goes on to suggest that evidence generated may be used '*as a political instrument where power interests can be obscured by seemingly neutral technical resolve*'. Limitations are recognised in the context of health provision, which becomes a complex process when engaging with the individual patient (UK Parliament, 2021a; de Almeida Andrade & Schlechta Portella, 2018; Miles & Loughlin, 2006; Fernandez et al., 2015). Developments in the definition of EBM have attempted to address these issues (Wyer & da Sylva, 2015; Greenhalgh, 2014) but the central focus on RCT evidence remains. In the UK the current online resource, BMJ Best Practice, a 'clinical decision support tool' for healthcare workers, still uses the original definition from Sackett et al. (2000) (BMJ Best Practice, 2022). References to EBM in the context of this study are concerned with how this controversial model has influenced the world of WHM in terms of the use of increasing modern herbal research evidence to inform clinical practice. There is a stark contrast between the positivist, epidemiological model of EBM and the holistic, individual WHM approach and this is discussed in sections 2.2-5 below.

There is now a huge body of health research evidence. Importantly for the current study, this includes a large number of papers on plants and plant constituents, mostly carried out since the turn of the last century. Studies are a mix of clinical and pre-clinical. Research involving plants can also be considered to be split into studies on whole plant extracts (WPEs) and

⁴ Searches on PubMed for a wide range of medical terms such as 'cancer', 'diabetes', 'cardiovascular', 'arthritis' all showed, on the graphical timelines, a noticeable increase in the rate of research publications in the years around the turn of the last century, with no identified exceptions.

studies on HSE or isolated constituents (Appendices 1 and 2 quantify this split in the body of research on a range of medicinal herbs). A major focus of the research on these identified HSE herbs is on active constituents, or the HSEs themselves. Active constituent research has long been desirable for the purposes of EBM and the rational scientific approach, as it allows precise measurement and definition, unlike the largely undefined complex WPEs (Weiss, 1988). For these HSE herbs where major active constituents have been so clearly identified and proposed to be central to therapeutic benefit, constituent research is particularly pertinent. It is this body of active constituent research that has led to HSE development. WPE research for these herbs may be viewed as less necessary to carry out. WPE research is also less scientifically controlled and measured, therefore does not suit modern scientific methods. There may also be less funding for WPE research it does not lead as clearly to marketable products. Although standardised herbal medicines have been prepared for over a century (British Pharmacopoeia, 1914) this investigation looks at these limited widely available OTC modern HSEs. They are considered as distinct preparations, clearly developed as the result of this body of modern research on the active constituents.

2.2 Increasing the focus on modern research in WHM

In the final decades of the 20th Century, with the focus on EBM methods, health research, including plant research, increased rapidly mainly through industry and university-based initiatives (Wohlmuth et al., 2002). There was a parallel move to increase the influence of modern research in UK herbal practice. This partial engagement with the research-based EBM approach that had been adopted by modern medicine, was part of a 'survival' strategy (Waddell, 2016) by some herbalists' leaders and professional associations (PAs) to increase public acceptance and approval and enhance the professional image of WHM (Conway, 2005; VanMarie, 2002). Early on, Weiss (1988) in Germany, where there has been a somewhat greater focus on rational phytotherapy than other countries, stated that WHM was '*fighting to be recognised as a science*' (p. ix) with growing interest from conventional medicine and the public. The aim was to separate the image of WHM from the existing traditional approach, rooted in folk medicine, changing the explanation of herbal therapeutic actions, to make it more scientific and conventional (Evans, 2008; Griggs, 1997; Nissen, 2008). VanMarie (2002) related this process of striving for wider acceptance of WHM to Dolby's (1979) model in which '*rejected knowledge becomes accepted....(when it) assumes the features of orthodox knowledge*' (p.4). This was particularly pertinent when regulation⁵ of the WHM profession was being considered (Day, 2007; Conway, 2005; Nissen, 2010) up to 2015. However the

government working group report 'The Walker Report (2015)' concluded that the available research evidence base relating to WHM was insufficient to support regulation. It was considered that regulation would offer undeserved 'legitimacy' to the profession.

In terms of training courses for herbalists, from the 1980s onwards there was an increased emphasis on research-based phytochemistry, which contrasted with use of herbs based on TK. This training was offered through what would become the 'College of Phytotherapy' in 1991, the focus being clearly stated as research-led phytochemistry rather than limited to only TK (Waddell, 2016). A further change related to strengthening the relationship between WHM and research in the UK around this time was in the form of the adoption of BSc herbal training courses by several universities⁶ from 1994 onwards. Since BSc degrees require a focus on scientific research, the contemporary growth of the body of plant research enabled the development of these courses and the training of herbalists in research methods. Some, but not all PAs (NIMH and CPP) required a BSc qualification for membership. A similar focus developed in central herbal texts for teaching; Mills and Bone's (2000) 'Principles and Practice of Phytotherapy' is notable as an important text that blended modern research with traditional WHM and in general contemporary texts accommodated different 'designations' of approaches to WHM within them (Waddell, 2016). The 2011 launch of the NIMH peer reviewed Elsevier 'Journal of Herbal Medicine' (JHM), with a focus on research evidence, was a further significant factor in placing WHM in the arena of the modern EBM approach. The editorial (Pendry, 2011) stated that WHM practice underpinned by sound research was vital to advance the profession in this way. In contrast, previous herbal journals that had sought to enhance the professional standing of WHM were not yet independently peer reviewed. Most recent examples were 'The British Journal of Phytotherapy', published for 11 years from 1990 by the College of Phytotherapy, as the name suggests, focused on scientific knowledge of plants. In contrast 'The European Journal of Herbal Medicine', published by NIMH for 10 years from 1994 placed a greater emphasis on TK.

Looking further back, it can be seen that these changes related to century-old drives for 'professionalisation'. The focus on the growing body of plant research was a new opportunity for WHM to assert itself as a recognised profession in the face of challenges from lawmakers and the medical profession. The formation, in the late 19th Century, of The National Association of Medical Herbalists (NAMH) (which later became the National Institute of Medical Herbalists (NIMH)) started the formalisation of WHM as a type of medical profession.

⁶BSc herbal training courses introduced at: [University of Westminster](#), University of East London (was the College of Phytotherapy), University of Lincoln, University of Leeds, Middlesex University, Edinburgh Napier University, The Scottish School of Herbal Medicine, University of Central Lancashire.

This contrasts with the common image of herbalists being simple purveyors of herbs. The aim was to take WHM away from non-scientific 'folk medicine' and influences such as the centuries-old influence of Culpeper's astrology (Wahlberg, 2010; Waddell, 2016; Brown, 1985). Herbal texts started to move away from the traditional 'Herbal', which presented herbs according to their 'virtues' according to TK. This was replaced by scientific 'monographs' that focused more on science-based 'actions', in what Treasure (2014) described as akin to a Kuhnian paradigm shift. In addition the development of the first professional journals by the NAMH, starting over a century ago, further supported this change of image (Waddell, 2016).

This long history of 'modernising' influences on WHM are considered by Waddell to have moved the profession away from the traditional focus on the WPE herbs, rather dwelling on professional skills and research. Indeed he notes that currently, detailed requirements for membership of the largest PA, NIMH, '*barely mentions herbs*' (p.25), but rather focuses on more general professional skills.

2.3 Controversy of research and HSEs in WHM

Now the changes concerning WHM and research have been outlined, including changing public perceptions, the discussion shifts to the controversy that exists in the herbal community surrounding modern research and HSEs.

The controversy of modern research in WHM has been widely documented (Conway, 2005; Griggs, 1997; Evans, 2008; Wahlberg, 2008; Snow, 2016; Jagtenberg & Evans, 2003, Nissen & Evans, 2012, Niemeyer et al., 2013). Evans (2008) and Jagtenberg et al. (2006) suggested that as systems of knowledge generation, modern research and TK, are not compatible or 'incommensurable' (Treasure, 2014). The positivist, epidemiological approach of the RCT contrasts with the holistic individual approach of TK, as explained below. Waddell (2016) stated that the nature of such research, and the focus on it in the WHM profession, risks separating herbalists from their (WPE) herbs. Niemeyer et al. (2013) warned of the risk of the research-based use of herbs challenging TK. They painted a picture of WHM practice based on highly processed products and novel research-based uses of herbs replacing traditional uses from years of clinical evidence, leading to a less complete system of knowledge. Similarly Treasure (2014) suggested that WHM could be under threat of extinction for these reasons, exacerbated by a fragmented body of herbalists. However, Niemeyer et al. (2013) also, more moderately and less catastrophically, recognised the modern challenge for WHM is how to integrate research with TK. Earlier Wahlberg (2008) described what he understood as the 'normalization' of the use of modern research within WHM, with integration of approaches. He did not view this as a scientific 'colonization' or take-over. Conway (2005) had believed that

concerns about a research focus destroying the essence of WHM were misplaced. He believed that these issues would reduce as more herbalists became university educated, with training in research methods included.

Reasons for the controversy of the research focus in parts of the WHM community have been based on the perceived incompatibility of most published studies in informing the commonly practiced traditional form of WHM. Knowledge obtained from modern research contrasts with TK which concerns evidence from clinical practice. Preparations used in research are often HSE, isolated constituents or highly processed extracts, compared to a focus on little-processed WPE in WHM (Nissen, 2015; Evans, 2008).

Considering the differences in how evidence is generated from TK compared to research, a major concern is whether findings from typical modern gold standard RCTs can be usefully extended to WHM practice (Snow, 2016). As outlined above, this is also a central question about the application of EBM in conventional healthcare, the positivist epidemiological RCT approach contrasting with treatment of the individual patient in all their complexity. In addition to these concerns, further issues relate specifically to the practice of WHM. In RCTs subjects with a specific condition (or none) receive either the same herbal preparation and dose, or placebo. Outcomes may focus on specific mechanisms of action. In WHM the focus is on the patient rather than the diagnosed condition, with individualised prescription of herbs, each patient receiving a tailored poly-herb preparation (as described by Nissen, 2015 and Niemeyer et al., 2013). In addition, compared to the positivist rational scientific basis of modern research, WHM practice may also incorporate the less scientific notions of vitalism and holism. The concept of vitalism (Lash, 2006) may be understood as '*life cannot be understood just through principles of physics and chemistry*' (Sheldrake, 1990, p79 in Evans, 2008) and holism as the '*...unity of (the) parts....(is) more than a sum of its parts*'⁷ (Nissen, 2011; Neimeyer et al., 2013). Niemeyer et al., (2013), discussed the challenge of integrating WHM with contemporary bio-medical research due to the assumptions of holism that do not allow for a more isolated focus. The validity of the research itself is not the central focus, but rather that the rational scientific methods may have limited applicability in the context of this common presentation of WHM practice. Nissen (2015) further suggested that the adoption by herbalists of non-native plants (such as typical HSE herbs, *C. longa* and *G. biloba*), following modern research evidence, conflicts with this traditional herbal practice which has developed from clinical experience. Niemeyer et al. (2013) specifically question the contemporary

⁷ This quote allegedly originated from Aristotle (Sarraf Yazdy et al., 2019)

common adoption of *Hypericum perforatum* (St. John's wort) in treatment of depression following research studies.

As well as the scientific methods discussed above, herbal preparations used in research studies also often contrast with traditional practice and the use of WPEs. They may be highly processed products or isolated active constituents. This does not allow for the perceived additional value of the complex WPE. It has delivered herbal knowledge based on 'products' or 'phytopharmaceuticals' made from plants rather than WPE or plants themselves (Evans, 2008; Jagtenberg & Evans, 2003). The applicability of such research to traditional WHM may be limited (Neimeyer et al., 2013).

This brings the discussion on to the similar controversy associated with HSE use, having been developed following such research on active constituents (for example as discussed by Evans, 2008, Waddell, 2016 and Nissen, 2015; 2010). These issues around concentrating active constituents are not new. There have been similar objections from herbalists up to over a century ago (Wahlberg, 2008; Brown, 1985; Nicholls & Robbins, 1991). For example (as identified by Waddell, 2016), Brown (1985) quoted Harry Orbell, writing in 'Herbal Therapy' in 1939/40, that '*when some active principles of herbs are used separately their therapeutic action is totally different to that obtained when the whole of the properties of the plant in question are employed*' (Brown, 1985, p77). In addition, Waddell (2016) suggested that WHM is set apart from other herbal traditions in that the major focus is on the herbs themselves, rather than a set of concepts underlying practice. Traditional models of WHM are not taught as explicitly in modern WHM BSc training courses as they are in other traditions such as TCM and Ayurveda. Waddell proposed that herbs are the equivalent of Illich's (1973) 'convivial tools' for WHM. Changing the nature of this central focus of WHM, the herbs themselves, in the production of HSE preparations, may therefore be more challenging than for other herbal traditions. Nevertheless those other traditions may also be considered 'at risk' from the influences of scientific developments (Wahlberg, 2008; Kaptchuk, 1983, p.24). This relative lack of a central philosophical basis in WHM compared to other herbal traditions may leave it more open to the 'scientificization' (Wahlberg, 2008) or medicalisation. This may happen when the less firmly rooted philosophy is more easily over-ridden (Barry, 2006).

The controversy of HSEs is similar but somewhat distinct from that of general research above. A central issue with HSE use, as indicated above, is that it challenges a core tenet of traditional WHM practice, which is the longstanding use of 'natural' WPE (Nissen, 2015) and the perceived benefit that this complexity brings (Niemeier et al., 2013). This contrasts with the identification and subsequent concentration of more isolated chemical compounds in HSEs. Waddell (2016) investigating herbalists' thinking and practice, discussed the existence of these

fundamentally different influences. He considered the more academic science-based approach compared to the non-scientific 'enchantment' with plants, which underlies the controversy of HSE. As Wahlberg (2008) pointed out herbalists generally prefer the WPE.

Considering differences in the nature of WPEs compared to HSEs, these complex WPEs typically consist of hundreds of constituents that are believed by some to act together in largely unexplained (and maybe practically inexplicable) 'synergy', to achieve a desired outcome in the body (Avila et al., 2011). Niemeyer et al., (2013) discussed complexity in WHM, proposing that plants work synergistically with humans and more recently Bone (2021, p.18) quoted Gertsch (2011) in defining herbs as '*intelligent mixtures*'*shaped by evolutionary pressures*'. In addition, the quality of WPEs are largely 'tested' by herbalists via organoleptics (using taste, smell touch and sight) and this is not possible with HSEs (Wahlberg, 2008; Waddell, 2016). Conversely, HSEs may be viewed by some as having less complexity, with a much greater concentration of a chosen chemical (or group of chemicals) which may have a specific desired effect in the body. Niemeyer et al. (2013) questioned the benefits of this relative isolation of constituents when behaviour of plant chemicals may be affected by their immediate environment in the WPE. Very recently, Bone (2021, p.18) quoted Sharma (1997) in explicitly criticising the scientific focus on active constituents. It was suggested that this focus has developed, not as a strength of the scientific method, but rather a weakness. It may not be suited to work with such complex systems as WPEs which defy the scientific requirements of measurement and control.

There are also other issues concerning HSE use which are detailed under discussion of individual herbs below. They include the potential therapeutic benefits of other non-standardised constituents for which there is initial, though limited, evidence. Another issue may be concerns that concentrated active constituents are associated with unwanted side effects (Evans, 2008), although limited research findings so far all suggest safety. This safety of HSEs, contrasts with evidence for herbs more generally. In Australia, Bensoussan et al. (2004) found substantial numbers and non-trivial adverse events reported by naturopaths and herbalists due to both herbs and nutritional supplements. Lin et al.'s (2009) survey of GPs found large numbers of adverse events with WHM. More recent safety issues were also concerned with manufactured environmental pollutants (Mirzaeian et al., 2021). Issues around safety of herbal medicines have been long documented and have included calls for regulation (Mosihuzzaman, 2012; Lin et al., 2009) and 'rigorously trained' herbalists (NIMH, 2021b) who use herbs safely. As noted by Chatfield et al., 2018, herbal products typically have far less safety data than would be needed for conventional . Work on herbal safety has been called for as a matter of urgency (Zhang et al., 2015). All these concerns do not relate to HSEs specifically

and it seems that they may be considered safer than other herbal preparations despite being highly concentrated and with a constituent profile unlike the WPE. In addition it is assumed that these HSE preparations which are widely available to the general public must have a good safety profile. Interactions with conventional medications remains a concern particularly since a high percentage of users of WHM also take GP prescribed drugs (Lin et al., 2009). This is why herbalists are trained to take account of herb-drug interactions. Other issues discussed with respect to individual herbs below are those of the effects of processing methods involved in HSE production. Neimeyer et al. (2013) had defined WHM as using plants with little or no industrial processing. In addition, there is evidence that active constituents may have reduced bioavailability when separated from the WPE. Some may also question the quality of HSEs. However, although tests on some HSE preparations have identified examples that do not contain what they claim in terms of active constituent content (e.g Campodónico et al, 2001; Lee et al., 2007), this can also be considered an issue for WPE preparations. WPEs do not offer any guarantee of constituent percentage and can vary widely. This may either be due to natural variation in plants, growing conditions, whether wild or cultivated, preparation methods or even adulteration or substitution with other plants or substances. This issue, which may affect both HSEs and WPEs may be a matter of opinion for individual herbalists. HSEs may be viewed as having consistency or alternatively there may be concern about manufactured characteristics.

Tensions around research and HSEs may also be complicated by concerns within the WHM profession around the continuing lack of proper legal status of herbalists within British law and thus the herbalist's role within the wider healthcare context. The use of research-based HSE products by herbalists and engagement with research may compensate somewhat for the lack of regulation or legitimacy. HSEs may be more 'acceptable' in conventional medicine settings, particularly since a major issue with acceptance of WHM is perceived lack of research evidence. In addition, the public may be reassured by herbalists who explain the body of research underpinning the products. As indicated above, it is not clear how influential this may be. The Wikipedia page (Wikipedia, 2021) on 'herbal medicine', which may be a source of initial information for the general public, supports HSE use rather than WPEs. It recognises herbal medicine as 'phytomedicine' and 'phytotherapy', which includes standardised herbal supplements but describes traditional herbal practice as '*Para herbalism.....(involving) pseudoscientific practices ...using...unproven medicines...'*.

Given these perceived incompatibilities between modern research methods and WHM, changes in the research body are happening. Mostly this is in the form of the increasing body

of WPE RCT research which has increased greatly over the last decade (Appendix 1;2; Table 3.1, p. 34). Research on polyherbal formulations typically used in WHM remains limited (Niemeyer et al., 2013; Walker, 2005). There have also been calls for alternatives to RCT research that better reflect complex practice (de Almeida Andrade & Schlechta Portella, 2018) but change has been slow. This has long been reported as an issue (Vickers & Zollman, 1999; Walker, 2005) and there are still only a few studies reflecting WHM practice that offers individual treatment (Niemeyer et al., 2013; Green et al., 2007; Hamblin et al., 2008).

2.4 Evidence for changes in public and conventional healthcare perception of WHM

Recent moves to update the modern image of WHM have been discussed. Despite the drive for regulation being unsuccessful, there is evidence that changes have nevertheless occurred. These concern the issue of increasing public and conventional medical acceptance of WHM, and more widely, CAM. Evans (2008) and Lin et al. (2009) in Australia, discussed how the move to make WHM more 'acceptable' to the public and in the conventional healthcare arena had progressed over the last 2 decades both in Australia and other countries. They cited the huge market for herbal products and demand for CAM healthcare as evidence for the continual increase in public interest over many years (MacLennan et al., 1996; Kellner & Wellman, 1997; 2002; Ernst, 2000; Williamson et al., 2003). This was reflected in findings of a systematic review in the UK from Posadzki et al. (2013a) where paediatric use of CAM, most frequently herbal medicine, was very popular. This was also found by MacLennan (2006; 2002; 1996; Australia). However this acceptance of OTC herbal medicine products by the public may not necessarily be related to the 'reassurance' of the research base (Bryden et al., 2018). Users of CAM more likely to hold non-scientific, 'magical' beliefs than practitioners (Little, 2012; 2009). Although public interest in OTC herbal medicines has greatly increased, acceptance by conventional medical practitioners is less clear. Evidence concerning CAM integration within the National Health Service in the UK is limited (Sharp et al., 2018b). Posadzki et al. (2012) carried out a systematic review of surveys in the UK, although pointing out the limited quality of identified surveys. They suggested widespread referral by NHS health practitioners to CAM services and Jarvis et al. (2015) found a positive attitude amongst UK GPs. This is despite a lack of CAM training for professionals to inform this practice. CAM training has no official place in UK medical training curricula, even for GPs who may see the widest range of opportunities for CAM prescription (GMC, 2019). Soliman & Bilszta (2021) found CAM teaching in undergraduate medical education inconsistent and clinical guidelines concerning CAM for clinicians in the UK are limited (Lorenc et al., 2014). It was noted however that UK provision of CAM training may exceed other countries, where most health professionals, in Australia and America, have called for training (Owen & Lewith, 2004; Pirota et al., 2000; Levine et al., 2003). Patel et al. (2017)

found most doctors wished to increase their CAM knowledge. In the UK and America, CAM training encouraged medical students to engage positively with patients' preferences for CAM, however this positivity waned with ongoing medical training and in medical practice (Furnham & McGill, 2003; Abbott et al., 2011). Maha & Shaw (2007) found widespread scepticism amongst UK academic doctors. Considering barriers to conventional healthcare professionals' engagement with CAM, more recently, Sharp et al. (2018a) also in the UK found GPs' lack of knowledge of CAM a barrier. Chang & Chang (2015) found nurses lacking in knowledge. Other major barriers include lack of regulation of CAM (Jarvis et al. (2015) and relative or perceived lack of research evidence (Patel et al., 2017; Lorenc et al., 2014; Maha & Shaw, 2007). Although the public may have embraced herbal medicine products, progress regarding health practitioner training and engagement with CAM or WHM and its practitioners is limited. This is despite evidence of open-mindedness, and is a concern given widespread herbal medicine use by the general public (Owen & Lewith, 2004), particularly since it continues to increase rapidly (Hexa Research, 2021).

2.5 Integration of modern research into WHM

Now the discussion moves on to consider the outcomes of this recent overt focus on research-based evidence in WHM. It investigates to what extent these methods have become 'integrated' into herbal practice, including HSE use. Although issues around research and HSE in general have a long history in WHM, little is known about how they have affected herbal practice or how they are currently regarded by herbalists themselves. Recent research evidence discussed below, suggests some integration of approaches, but this evidence is so far limited. It does not offer a clear picture of the state of current or past practice.

There have been concerns about the scientific research-based approach 'taking over' WHM, although evidence is largely from herbalists and naturopaths in Australia (e.g. Braun et al., 2013; Evans, 2008;2009; Casey, 2009; Singer & Fisher, 2007). Greater integration of research-based evidence in Australia is related to the relative support and pressure on PAs to modernise and present themselves as EBM-based (Ooi et al., 2018) compared to the UK. Support and legitimacy for naturopathy has come from the state (Baer, 2006) and there is opposition to 'non-scientific' training in tertiary training institutions (MacLennan and Morrison, 2012). As early as 2009, Casey argued that 'mainstreaming' of WHM was occurring in Australia, whereby integration of approaches leads to conventional healthcare methods becoming dominant. The risk of WHM losing its identity was suggested. This was also indicated by Evans (2009) and Singer & Fisher (2007) who argued that with 'co-option' of WHM by biomedicine, TK was in danger of being side-lined. Singer and Fisher (2007) in Australia also suggested a split in the WHM community between 'science-orientated' and 'traditional' herbalists with the latter in

'rebellion' against changes to herbs brought by research evidence. Evans (2008) went as far as suggesting that research-based evidence was replacing traditional knowledge in modern practice in Australia. Later in Wardle & Sarris (2014) student naturopaths were conversely found to favour an approach that '*focuses heavily on EBM*' in their training and research-based evidence was considered '*essential*' for practice (Braun et al., 2013; Wardle & Sarris, 2014). It has been proposed that there is no conflict between use of research-based evidence and TK (Ooi et al., 2016) although there remains a tension. Integration as work in progress for naturopaths was also suggested by Ooi et al. (2016), and found in interviews (Steel and Adams, 2011). More recent evidence suggests that practice is indeed strongly focused on research evidence (Ooi et al., 2018). There are still ongoing calls for integration with conventional healthcare and professional recognition (Leach et al., 2021). This ongoing integration is still viewed by some as necessary in Australia for mainstream acceptance and therefore survival of the practice of WHM and naturopathy (Ooi et al., 2018). Bone (2021), in his recent book '*Functional Herbal Therapy*' discussed his realisation that, rather than one approach suppressing the other, TK could be blended with research-based evidence and produce a robust modernisation of WHM, as supported by Singer & Fisher (2007) who stated that herbalists are highly skilled in this process of blending.

Recent findings from America and Canada have suggested a modest integration of approaches but with cautions. Although Cordell & Colvard (2012) in America called for a research base for traditional medicine, other ideas which focus rather on integration are more moderate (e.g. Neimeyer et al., 2013). More recently Snow et al., (2017) surveying herbalists in America found a generally positive attitude towards research studies. American naturopaths showed a 'cautious embrace' (Goldenberg et al., 2107), and naturopaths in Canada recently reported moderate to high use (Aucoin et al., 2021). Snow (2016) describes this process as practitioners wrestling with the competing approaches before managing to integrate them into a form that is more acceptable in conventional settings, providing a shared professional language, without replacing personalised treatment. However, Treasure (2014) proposed that modern WHM, due to this clash of paradigms is in a Kuhnian crisis (subsequent to the first one he described above). He suggested that a paradigm shift taking the focus back to the pre-modern 'natures or virtues' of the herbs, rather than research-based 'actions', is needed for WHM survival.

In the UK reported change appears more moderate than in other countries, although there are far fewer studies and notably less pressure on practitioners to integrate research-based evidence and TK, particularly compared to Australia. Evidence of integration was recently found in 2014-15 herbalist interviews by Waddell (2016). He found that collaboration between TK and research was largely seen as possible by participants, without the need for WHM to be

'taken over' by science. Herbalists reported being able to accommodate such seemingly conflicting approaches. Similarly, Wahlberg (2008), although drawing on herbal texts rather than practitioners directly, suggested that UK herbalists rely on both research-based evidence and TK. He proposed that the effectively blend the seemingly opposed paradigms through the process of 'normalization' whereby the methods of scientific research are integrated with TK. Waddell (2016) concluded that it is now accepted that the scientific approach has become more prominent in WHM, at the expense of TK. Earlier studies nearer the beginning of the century found the beginnings of this moderate integration, although VanMarie (2002) argued that despite training in research methods being adopted into UK herbal training, actual practice remained largely traditional. In another early study, considering the nature of modern herbal medicine practice in the UK from 2004-5, Nissen (2015) confirmed the central notion of 'naturalness' or '*shared humanity within the organic world*' (p.174). This contrasted with the '*rational scientific*' approach that has been included as a common element in modern herbal training courses. She suggested that (only) a very limited blending of approaches was starting to happen at that time. Nissen (2010), from survey data in 2005, offered other very limited evidence for acceptance of research-based evidence although finding that most practitioners valued the title 'medical herbalist'. This may reflect changing attitudes following the introduction of more academic training.

In addition, modern approaches such as 'Integrative Medicine' aim to incorporate CAM approaches, including WHM (Chatfield, Salehi, Sharifi-Rad, & Afshar, 2018) with modern medicine (Kanherkar et al., 2017). Conway (2005) suggested that WHM has more in common with conventional medicine than many CAM therapies. More recently The Herbal Alliance has been established, which aims to support WHM (The Herbal Alliance, 2021) and states as one of eight founding principles '*We integrate vitalistic and scientific worldviews*'. Scientific research has historically always had an influence on the practice of herbal medicine (Willard & Caldecott, 2021), therefore it is to be expected that research evidence is becoming integrated into UK WHM.

It might be proposed that evidence of integration of modern research into WHM practice is also found in the widespread adoption or re-adoption of herbs following such studies (including HSE herbs considered here as well as others such as nettle (*Urtica dioica*) root), suggesting acceptance or use of the increasing body of research. These herbs, are likely widely used by herbalists, as suggested by the author's previous study (Sprung, 2016) which found over 90% of respondents reported use of *C. longa* WPE and / or HSE. These limited HSE herbs are also included in the large majority of recent herbal texts written for herbalists (e.g. Bone &

Mills, 2013; Menzies-Trull, 2013; Kuhn & Winston, 2008; Fisher, 2009; Thomsen & Gennat, 2009; Ross, 2010), although the influence of these texts is not specifically known.

Limited evidence from Sprung (2016) suggested that overt research influence on WHM practice was minimal, despite showing overwhelming adoption of both the WPE and HSE of *C. longa*, a herb for which evidence for modern use is largely based on HSE research. Although justification for use of the WPE preparations of HSE herbs, particularly if the dose used does not reflect that in HSE research, may be questionable (Evans, 2008), use may have been related to other factors. These factors influencing use of *C. longa* were suggested, in Sprung (2016), as uncritical acceptance of the large volume of research, supplement company seminars, reported positive clinical evidence from practice and convenience of use.

Considering this evidence above for adoption of research by practitioners of WHM, evidence from the arena of conventional healthcare offers insight. Health professionals' adoption of the research-based EBM approach in their practice has been found to be inconsistent (Mascia et al., 2013;2014; Mascia & Cicchetti, 2011; Scurlock-Evans et al., 2015) and a review of 29 studies on conventional doctors (Cunningham et al., 2019) found a 'disproportionate' influence from other healthcare professionals and evidence from clinical practice, compared to research. This is despite the theoretical central importance of the EBM approach, and positive engagement of medical students during teaching (Shaker et al., 2020). Teaching may however be inconsistent (de Girolamo et al., 2020). This may suggest that concerns about WHM being 'taken over' by research may seem unlikely if it is limited in practical uptake for even those professions that are proposed to be firmly rooted in EBM.

Many studies have considered the integration of research with WHM, as discussed above. There is however very little evidence specifically concerning the adoption of HSE preparations by herbalists and how this happens. There have been general concerns about the increasing use of a wider range of less highly standardised but yet 'research-based' herbal products, but not in the UK (e.g. Niemeyer et al., 2013; Treasure, 2014; Evans, 2008). Sprung (2016) provided initial evidence of widespread use of *C. longa* HSE amongst NIMH herbalists, with 40% reporting use, suggesting that previously controversial HSEs were becoming increasingly important in herbal practice. There was little evidence of this being due to the influence of research, reflecting existing evidence of limited practical influence of research in UK WHM (Nissen, 2015; Waddell, 2016). Influences on use were rather related to clinical evidence from practice, with a strong focus on the Lamberts preparation suggesting an influence of promotion that included frequent free seminars that were offered to herbalists.

Chapter 3: Evidence that may inform choice of preparation, with specific consideration of individual HSE herbs

Having outlined the controversy surrounding the issues of modern research and HSEs, and their partial incorporation into WHM practice, the final discussion in this introductory section concerns available guidance and influences on choice of preparation. There is little evidence available to inform this choice whether from training courses, PAs or herbal texts. Decisions may be based on underlying beliefs about practice, as discussed above. In addition there may be other influences related to the individual herbs. These may be historical use, recommendations from other herbalists, evidence from herbalists' own clinical practice, supplement company information and the increasing body of research studies. Such information varies widely between different herbs that are available as HSEs and therefore they must be considered separately for informing choice of preparation. The four herbs discussed below have been chosen for discussion as they are considered the most likely herbs to be used as the HSE by herbalists and they all differ in terms of available data that may influence choice of preparation. Chosen herbs are all commonly found in modern herbal texts and are also recommended as the HSE preparation in varying numbers of texts (see Table 3.2. p.36). They are also readily available OTC as HSEs, specifically discussed here in the form of Lamberts Healthcare products. Lamberts Healthcare was by far the most popular supplement company reportedly used for the HSE in the author's previous study on *C. longa*, therefore products are considered representative of those readily available to herbalists. The four herbs discussed also have the largest number of results for a search of human RCTs concerning HSEs (see Table 3.1, p.34). RCTs, being considered the 'gold standard' for research evidence are considered here to provide evidence for HSE use, rather than the much larger body of mostly pre-clinical research which offers limited evidence for clinical application (see Appendix 2 for details of the pre-clinical research body). This influence of HSE or active constituent research on the use of these herbs contrasts with the large number of other herbs used in WHM which are not available as HSE. The use of these non-HSE herbs is based both on traditional use, in WHM and other herbal traditions⁸, and recent research⁹, but the body of research does not focus on identified active constituents as it does for the HSE herbs, as shown in Table 3.1. It is clear from this data, that almost all RCTs concerning the HSE herbs discussed here are on the HSE preparation, unlike typical WPE herbs, and therefore research evidence strictly only supports the use of the HSE. It has been proposed (Evans, 2008), that following evidence from HSE research should strictly lead to only HSE use in practice or WPE doses that are equivalent

⁸ For example the many 'adaptogens' adopted from Traditional Chinese Medicine (such as *Panax ginseng*, *Astragalus membranaceus*) together with modern research evidence.

⁹ For example the novel adoption of nettle root (*Urtica dioica*), following modern research studies.

to HSE doses in studies, since research evidence is largely lacking for WPE use of these herbs. However, there are more influences than simply the HSE RCT research body, as discussed below for the individual herbs. A comparison of the herbs, as detailed below, offers information that may inform choice of preparation. First, the discussion of *C. longa* HSE suggests that the HSE may offer a convenient high dose or replication of research studies, but there is also evidence for use of the WPE from research and historical use. Herbal texts focus more on the traditional lower dose WPE for this herb that has been overwhelmingly adopted into WHM. After this, findings suggest *S. marianum* HSE may offer a convenient form for the recommended dose as used in research studies. Although the body of research is less compelling than for *C. longa*, use of *S. marianum* HSE is supported by a greater recommendation in herbal texts than for *C. longa* HSE, with only limited evidence of the influence of the long traditional WHM use of low dose WPE. Similarly *G. biloba* HSE also offers a high dose as used in research studies and is the most widely recommended HSE in herbal texts, rather than the WPE. When recommended it is as a high dose HSE 'equivalent' and may not be practical to administer. This reflects a lack of traditional use for the leaf and therefore presumably rather a focus on research evidence, although that evidence is limited. Finally, *S. serrulata* HSE also has mixed research evidence for clinical use and the relatively low HSE dose may be conveniently replaced by the WPE, particularly since it has a continual history of traditional use supporting use of the WPE.

For each individual herb outlined below, details of the herb and identified active constituents are provided, followed by historical use of WPE and HSE, details of a typical HSE and recommended doses and preparation of the herbs in herbal texts (see Table 3.2, p.36). This is followed by research evidence that may influence choice of HSE or WPE and any evidence from clinical practice. A comparative summary of the evidence is provided in Table 3.3 (p. 40). The discussion of *C. longa* is longer than the other herbs as there is more data available.

Table 3.1: Numbers of published ‘human randomised controlled trials’ on PubMed between 2000 and 2021, as of 3.1.21. Numbers of studies found for a range of herbs and their major active constituents (if any specifically identified)

Search terms (Latin name of plant and major identified active constituents)*	No. of relevant studies located on active constituents or HSE on PubMed with ‘Human Randomised Controlled Trial’ ** filters	No. of relevant studies located on WPE on PubMed with ‘Human Randomised Controlled Trial’ filters
Herbs that are commonly available as HSE products		
<i>C. longa</i> or curcumin or curcuminoid	316	20
<i>G. biloba</i> or bilobalide or bilobalide	327	3
<i>S. marianum</i> or silymarin or silibinin	123	0
<i>Boswellia serrata</i> or boswellic acid	54	2
<i>S.serrulata</i> or <i>repens</i>	93	0
Examples of herbs that are not commonly available as HSE products ††		
<i>Aesculus hippocastanum</i> (horsechestnut) or escin or aescin	34	10
<i>Arctium lappa</i> (burdock)	0	5
<i>Ballota nigra</i>	0	0
<i>Berberis vulgaris</i> (barberry) or berberine	77†	2
<i>Centella asiatica</i> (gotu kola) or asiaticoside	1	40
<i>Echinacea</i> spp. or alkylamides	1	58
<i>Eleutherococcus senticosus</i> (Siberian ginseng)	0	31

<i>Glycyrrhiza glabra</i> (liquorice) or glycyrrhizin	19	18
<i>Hypericum perforatum</i> (St. John's wort) or hypericin or hyperforin	0	149
<i>Matricaria chamomilla</i> or <i>Matricaria recucita</i> (chamomile)	0	27
<i>Paeonia lactiflora</i> (paeony) or paeoniflorin	0	19
<i>Rosmarinus officinalis</i> (rosemary) or rosmarinic acid *	3	17
<i>Taraxacum officinale</i> (dandelion)	0	5
<i>Thymus vulgaris</i> (thyme) or thymol	16	11
<i>Urtica dioica</i> (nettle)	0	24
<i>Withania somnifera</i> (Ashwaganda) or withanolides	0	25
<i>Zingiber officinale</i> (ginger) or gingerol or shagaol	1	221

* There are many constituents that are found in more than one plant, such as rosmarinic acid, but they are included if they are major constituents.

** 'Human randomised controlled trial filters' were used to reduce the studies to a manageable list; there will be other articles that may be useful to herbalists but the RCT is used as a measure of study quality in the EBM approach.

† Although there are many RCTs on the active constituent of *B. vulgaris*, berberine it is not recommended in herbal texts as the HSE so is not included in the discussion as it is assumed that it is therefore not widely used by herbalists; there is also no evidence for the availability of such as product.

†† These non-HSE herbs examples are widely represented in herbal texts as a measure of commonly used herbs in WHM (noting that several have been adopted from other herbal traditions).

Table 3.2: Recommended preparations of the main identified HSE herbs and details of doses* in a range of herbal texts

Recommended form of herb stated in Herbal Texts **	<i>C. longa</i>	<i>G. biloba</i>	<i>S. marianum</i>	<i>S. serrulata</i>
The Healing Power of Herbs, Murray, 1995	HSE 400mg - 600 mg curcumin x 3 per day WPE not recommended as dose stated as 8 – 16 g x 3 per day which is not practical	HSE 40 – 80 mg x 3 per day Non-standardised WPE not recommended	HSE 70 - 210 mg silymarin x3 per day (higher doses preferred) WPE not recommended	HSE – 160 mg x 2 daily WPE not recommended as not practical for similar dose
Herbal Medicine, Weiss, 1988	WPE ('gallbladder remedy') 'pinch dose'	HSE unspecified dose	WPE 20 drops of tincture 3 – 4 x per day; or in a tea (unspecified amount)	WPE unspecified
Potter's New Encyclopedia of Botanical Drugs and Preparations, (Wren, 1989)	No preparation stated . 'Seldom used medicinally, However recent research has shown many useful properties...'	No preparation stated	HSE 420mg daily	WPE 0.5 – 1 g dried berries
Bartram's Encyclopedia of Herbal Medicine, 1998	WPE 1 – 2 g daily	WPE 'large doses may be required' of leaves as tea, possibly HSE / tablets 250 mg x 1-2 daily	HSE 80 – 200 mg x 3 daily WPE half a tsp as a tea or 10 - 30 drops of tincture	NA
Herbal Medicine Healing and Cancer, Yance, 1999	HSE and WPE unspecified amount	Not stated	HSE unspecified amount	Not stated

German Commission E monographs, Blumenthal, 2000	WPE 1.5 – 3 g dried powdered rhizome; or 'equivalent preparations'	HSE 120 – 240 mg HSE x 2 - 3 per day	WPE: 12 - 15 g dried seed; 'Formulations equivalent to 200 - 400 mg of silymarin, calculated as silibinin' – it is assumed this indicated HSE.	WPE 1 - 2 g saw palmetto berry HSE 320 mg lipophilic ingredients
The medicinal Flora of Britain and Northwestern Europe, Barker, 2001	NA	No preparation recommended	WPE 'powder' (unspecified amount) or 2ml x 4 per day of 1:5 in 25% alcohol	NA
Medical Herbalism, Hoffmann, 2003	NA	HSE 120 - 240 mg per day	HSE 170 – 600 mg per day	WPE 1 – 2 ml x 3 per day of tincture (1:5 in 60% alcohol) or 2-4 tsp berries or 0.5 - 1g dried (from BHP); HSE 320 mg (CommissionE)
Herbal Therapy & Supplements, Kuhn & Winston, 2008	WPE 1.5 – 4 g daily HSE 350mg x 2 per day ('It is believed that the the curcumin extract is stronger (superior) to whole <i>C. longa</i> extracts, but there are no studies to prove this')	HSE 40 – 80 mg x 3 per day WPE 1:2 70% alcohol tincture, 3 – 5 ml x 3 per day ('The tincture is significantly less effective than the standardised preparations and the tea has little or no activity')	HSE 140 – 160 mg silymarin x 3 per day WPE 1:4 70% alcohol tincture 3 – 5 ml x 3 per day (for tincture, 'need to administer high amounts....to obtain adequate silymarin...used cautiously in patients with liver damage')	WPE 2 – 6 g per day HSE 320 mg daily
Materia Medica of Western	NA	WPE 2 – 3 g x 3 per day HSE 40 mg	WPE 2 – 4 g x 3 per day	WPE 0.5 – 1 g x 3 daily HSE dose of 320 mg daily included as

Herbs, Fisher, 2009				explanation of preparation used in clinical trials
Phytotherapy Desk Reference Thomsen & Gennat, 2009	WPE 12 g per day	WPE 9 - 10g per day dried leaf HSE 120 – 240 mg	WPE 6 – 12 g per day	WPE 1.5 - 3 g per day
Principles and Practice of Phytotherapy, Mills & Bone, 2013	WPE 4 g dried powdered rhizome Preferable as WPE for 'anti-inflammatory effects, since aqueous extracts devoid of essential oil or curcumin also have shown some activity'.	HSE 120 – 240 mg daily dose	HSE - Three to four 200 mg tablets per day; higher doses for severe liver damage WPE 4 to 9 g /day of seed	HSE 320 mg daily WPE 1.5 to 3 g of dried berries per day
Herbal Medicine Pharmacopoeia, Menzies-Trull, 2013	WPE dose of 4 g dried powdered rhizome	WPE dose 3 g of dried leaf 'Dry leaf extract' 80 mg (this is interpreted as HSE)	WPE dose 2 g dried seeds 'dry extract' 200 mg (interpreted as SE)	WPE dose of 4 g dried fruit 'Dry extract' 300 mg (interpreted as HSE)
Encyclopedia of Herbal Medicine, Chevallier, 2016	WPE dose of 3 x 5ml tincture (1:5), 3 x tsp of powdered rhizome daily or 20g daily in aqueous preparation	WPE dose of 1 tsp tincture (1:5) 2-3 x per day; unspecified 'tablets' may be assumed to be HSE	WPE dose of 20g daily in aqueous decoction. 'Tablets' are assumed to imply HSE	WPE dose of 1tsp tincture daily (1:5),

* It is acknowledged that different preparations for what appears to be an 'equivalent' dose contain a different balance of constituents and bioavailability.

** The list consists of those which were identified as including specific clinical dosage recommendations as appropriate for herbalists' practice, and the author's clinical judgement was used to inform this decision making. They were obtained from online searches for herbal texts; websites searched were AeonBooks.co.uk (a publisher for alternative and complementary medicine) as well as an Amazon.co.uk search for 'herbal medicine' in 'Books'.

In addition the author's own library was used. Access to books included ownership by the author, online access, requests for access to other herbalists and direct purchase.

Table 3.3: Comparative summary of evidence that may inform choice of preparation of the major identified HSE herbs

Evidence	<i>C. longa</i> rhizome	<i>S. marianum</i> seed	<i>G. biloba</i> leaf	<i>S. palmetto</i> berry
Major identified active constituents and use	Antiinflammatory and antioxidant curcuminoids	Antioxidant and hepatoprotective Silymarin	Antioxidant, antiplatelet and cognition-enhancing <i>G. bilobalides</i> and bilobalide	Lipophilic compounds used for prostate health
Current use of herb in WHM	Widespread current use of WPE and SE	Unknown	Unknown	Unknown
History of use	Long history of use in non-WHM traditional medicine for digestive issues	Long history of traditional WHM use which fell out of favour before modern research	No history of traditional use for the leaf	Long history of un-interrupted use in WHM
Recommended preparation in texts	Largely WPE, lower dose than typical HSE	HSE or less convenient high dose 'equivalent' WPE	Largely HSE or less convenient 'equivalent' dose WPE	HSE and WPE both recommended, reflecting similar traditional and research doses
HSE dose	HSE tablets typically offer a high dose equivalent to 10g WPE, reflecting research, traditional dose being smaller	HSE may offer dose equivalent to 8g WPE, much higher than traditional dose	HSE may offer dose equivalent to 6g of WPE, which may be impractical	HSE dose equivalent to 3g of dried berries, reflecting traditional dose

Research evidence for use	Large body of rapidly increasing RCTs on HSE offering strong evidence for use	Mixed RCT evidence for HSE use.	Mixed RCT evidence for HSE use, possible reducing research interest	Mixed RCT evidence for HSE use
Research evidence supporting WPE use	Considerable pre-clinical initial evidence for therapeutic benefit from non-curcuminoid compounds and increasing evidence for WPE use in RCTs	Some very limited pre-clinical evidence for benefits of non-silymarin compounds and WPE	Virtually no evidence	None found
Evidence for safety of HSE	HSE safe at high doses	HSE safe at high doses	HSE safe at high doses	Good safety profile in RCTs

3.1 *C. longa*

The part of *C. longa* currently used medicinally in WHM is the rhizome. The major identified active constituents are a group of chemicals called curcuminoids. These are a group of linear diarylheptanoids, including curcumin, which have been shown to have clinically significant anti-inflammatory and antioxidant actions, discussed later.

C. longa has a long history of use as a plant medicine, going back at least 2500 years (Gupta et al., 2013; Bone, 1991). Although it has not played a significant part in traditional WHM (Tobyn et al., 2011), it has long been a part of the traditional practice of Ayurvedic herbal medicine, TCM and Japanese Kampo medicine for a range of health issues digestive and liver problems, inflammation and pain (Wichtl, 2004; Bone, 1991, Murray, 1992;1995). This long history of use led to research interest, with the identified active constituents, the curcuminoids (largely curcumin) being identified as having anti-inflammatory and antioxidant properties from the 1970s onwards (Bone, 1991; Wren, 1989, p.270). However, little mention has been made of the herb in twentieth century WHM literature until near the end of the century. Grieve (1931c) in the famous historical text (The Herb Society, 2018) 'A Modern Herbal' stated that it is '*rarely*

used medicinally' and there was no entry in Law (1973) or Priest & Priest (1982). The German Commission E monograph (1985) (in Bisset and Wichtl, 2001) stated use as '*Dyspeptic complaints*' and Weiss (1988), recorded only '*limited use as a gallbladder remedy*' reflecting use in other herbal traditions. Following this, Wren (1989) wrote that it was '*Seldom used medicinally, however recent research has shown many useful properties...*' (p.270) showing that attitudes may have been starting to change around this time, following accumulating pre-clinical research evidence. Although by no means widely represented at this time (e.g. no entry in Mills, 1991; de Bairacli Levy, 1991), Bone's (1991) article about *C. longa* discussed research evidence and stated that this '*unique combination of properties.....should afford turmeric an important future role in the prevention and treatment of major modern disease processes*' (p.51), predicting the increase in use that was to come. Indeed, soon after this *C. longa* started appearing in herbal texts as a useful herbal medicine, with details of research evidence as well as traditional use (Murray, 1992). Indeed Murray (1992) stated '*Curcumin may be the most potent anti-inflammatory compound in botanical medicine*' (p.327). Indications for a wide range of uses, largely digestive and inflammatory conditions, continue as time goes on (Murray, 1995; Bartram, 1998; Duke, 1997), however there was still no mention in The British Herbal Pharmacopoeia (BHMA, 1996) or Hoffmann (1996). At this point, although research studies were increasing rapidly, clinical evidence was lacking. A PubMed search suggests that RCTs were limited until around 2005; prior to this only 3 RCTs were identified, all investigating digestive function in line with traditional Ayurvedic use. However a general search for 'curcumin' and 'antiinflammatory' gave 964 results up to that point, 'curcumin' and 'antioxidant' gave 427 results and 'curcumin' and 'cancer' gave 487 results, pointing the way towards clinical uses in the future, although at this stage extrapolation of results to hint at clinical application was required. Although medicinal use of *C. longa* was still omitted from some texts at the beginning of the 21st Century (Hoffmann, 2003; Lust, 2005) increasing numbers record *C. longa* useful in inflammatory and digestive conditions. This reflects both recent research and traditional use from other schools of herbal medicine (Bisset & Wichtl, 2001; Mills & Bone, 2003; Bone & Mills, 2013; Herr, 2002; Kuhn and Winston, 2008; Thomsen & Gennat, 2009; McIntyre, 2010; Menzies-Trull, 2013). More recently Stansbury (2018a) stated that *C. longa* has been '*long used for all manner of inflammatory processes*' (p.62) and *C. longa* is widely recommended in all 4 of her Herbal Formularies for Health Professionals (Stansbury, 2018a;b;c;2020) covering all major systems of the body. According to contemporary herbal texts it appears that *C. longa* has been overwhelmingly adopted into WHM practice and this is supported by the author's recent study (Sprung, 2016) that found over 90% of UK NIMH members surveyed reported its use.

WPE *C. longa* rhizome typically contains 3-4% curcuminoids (Tayyem et al., 2006) whereas the HSE typically contain 95% curcuminoids, as tablets or capsules. For example, Lamberts Healthcare Ltd. (2021a) states that its 95% curcumin tablet is equivalent to 10g of whole dried *C. longa* rhizome¹⁰. This dose of the equivalent of 10g of dried rhizome is a large dose compared to the German Commission E Monographs (Blumenthal, 2000) which recommends 1.5-3 g daily and may reflect typically smaller traditional dosing. Using a tablet of *C. longa* HSE may therefore be considered a convenient way of administering a very large dose of the WPE. However, since practice is based on herbal prescribing for the individual patient, the HSE may be viewed as an excessively large, fixed dose that cannot be adjusted. 10 g of whole *C. longa* rhizome dried powder is about 2 heaped teaspoons, which is a large volume of powder to consume daily, although not impossible. Recommended daily doses in contemporary herbal texts (Table 3.2, p.36) largely agree with Blumenthal (2000), suggesting a greater emphasis on traditional dosing. Two recommendations are much higher and roughly equivalent to the HSE dose (Thomsen & Gennat, 2009; Murray, 1995) and may be rather stating an equivalent WPE dose for a typical HSE. This is assumed to place a greater value on research findings than traditional use.

The German Commission E monographs (Blumenthal, 2000) recommends *C. longa* in the WPE form, with no specific mention of the HSE, and more recent texts all recommend the WPE, with occasional additional inclusion of the HSE. This is despite the large volume of research evidence for use of HSE *C. longa* that has been continually accumulating and is discussed below. No texts apart from an older text, Murray (1995), recommend only the HSE, possibly reflecting a response to the new body of curcumin research at that time. Comments however vary in their focus between texts and even those that concentrate on research disagree on recommended preparation. For example, Mills and Bone (2003;2013), although focusing on research recommend only the WPE *C. longa* for its anti-inflammatory effects, explaining that non-curcuminoid studies also show activity, with Bone (1991) having been discussing the potential benefits of non-curcuminoid constituents for decades. These non-curcuminoid constituents are better represented in the WPE than the HSE. In contrast Kuhn & Winston (2008), also focusing on research evidence, state '*It is believed that the curcumin extract is stronger (superior) to whole C. longa extracts, but there are no studies to prove this*' (p.450), suggesting that the HSE is preferable. Between the two texts there is a fundamental difference in the most important therapeutic aspects of the herb, the belief that the HSE is stronger,

¹⁰ Lamberts Healthcare Ltd is given as an example here as it was by far the most popular supplement company used in the author's previous study, therefore products are representative of those readily available to herbalists.

compared to the evidence that it may omit important constituents. It is not at all clear which is more therapeutically significant.

Overall, the herbal texts in Table 3.2 recommend *C. longa* WPE far more often than the equivalent HSE, although it is not clear how influential herbal texts are. Sprung (2016) did not find any overt evidence of the influence of herbal texts on choice of preparation.

Moving on to a review of research studies, these may offer some limited evidence for choice of *C. longa* preparation (Appendix 3). The very large body of research evidence on any preparations of *C. longa* included over 300 RCT results of which more than 90% of studies were published since 2010, showing how rapidly research is accumulating including in terms of more reliable 'gold standard' RCT evidence. Appendix 1a shows how numbers of RCT studies published yearly on *C. longa* is continually increasing. For example there were only 7 entries recorded in 2010 but 71 in 2020. This represents a large body of rapidly increasing evidence for use of the HSE as 94 % of RCTs identified in Table 3.1 related to the HSE rather than the WPE. RCTs have investigated *C. longa* in terms of its anti-inflammatory and antioxidant properties in a wide range of inflammatory conditions. Considering evidence from 13 most recent reviews and meta-analyses of RCTs, identified on PubMed from 2020-1 (Appendix 3) that investigated a range of inflammatory conditions, the evidence was positive for efficacy of the HSE in all studies and largely focused on ulcerative colitis (4), osteoarthritis (2), depression (2) and non alcoholic fatty liver disease (2). This represents a large evidence base for a wide application of the HSE that includes and expands on traditional use, albeit at larger doses of curcumin. The choice between traditional dosing, with historical evidence, and the HSE is not clear as there is evidence for both.

Studies that may specifically inform the HSE debate concern those that investigate the differences between the preparations. This may be from WPE studies directly, comparison of the HSE to the WPE in the same study, or indirect comparison by investigating the therapeutic benefits of non-curcuminoid constituents, as outlined below.

Although virtually all research on *C. longa* concerns the HSE, there are several RCTs that used WPE *C. longa* and these appear to be increasing in line with the increase in *C. longa* HSE studies in general. Although 9 (43%) of these 21 studies were published in 2019-20, there is only little evidence that there is increased interest in research on the WPE as 31% (90/286) of *C. longa*/curcumin/curcuminoid RCTs listed were published in 2019-20, reflecting the rapid increase in studies. Twenty human RCTs published between 2010-2020 were located on PubMed that all supported the efficacy of WPE *C. longa* (or *C. longa* in combination with one other herb). RCTs from 2019-20 consisted of powdered *C. longa* (Manarin et al., 2019;

Srinivasan et al., 2019; Ghaffari et al. 2019; Heidari-Beni et al., 2020; Adab et al., 2019; Vaughn et al. 2019; Maithili et al., 2015), aqueous *C. longa* extract (Uchio et al., 2019; Asada et al., 2019) and ethanolic extract (Roa et al., 2019) and addressed aspects of inflammation and lipid balance. However WPE studies are still limited, maybe due to lack of funding, and there are other developments in *C. longa* products and research which may secure more interest. These include increasing the bioavailability of curcumin by a variety of methods (Dei Cas & Ghidoni, 2019) or investigating local action in the digestive tract (Lopresti, 2018) which may attract more focus than investigating the WPE.

Despite increasing studies on the WPE *C. longa*, there is still little evidence comparing the HSE directly to the WPE and it is limited to one clinical study and several pre-clinical ones. The author suggests that these existing limited number of studies, although largely pre-clinical, are perhaps more informative concerning therapeutic use than might be expected from pre-clinical studies in general. This is because the evidence sought relates to the comparison of the preparations, rather than needing to theoretically extrapolate results into a clinical setting, which is less reliable and is usually a major limitation of such studies. Only one recent clinical study was identified that compared relative curcumin absorption in WPE turmeric compared to curcumin; absorption of curcumin from the WPE was about 4-5 times as great (Ahmed et al., 2019). However, White et al., (2019) carrying out a systematic review of liver enzyme levels in non-alcoholic fatty liver disease identified 4 RCTs, and found a 3 g daily dose of WPE *C. longa* pieces ineffective in one study (Navekar et al., 2017) compared to similar doses of curcumin in HSE form in 3 other studies (doses from 140 – 300 mg). HSE preparations consisted of curcumin complexed with lipid-based absorption enhancers, unlike the WPE which was administered alone and it is possible that this made a difference to outcomes.

In addition, several pre-clinical studies also all found in favour of the WPE compared to the HSE. All studies identified suggested an advantage of the whole plant compared to HSE, including increased bioavailability of curcumin, anti-angiogenic effect, superior tissue healing, immune benefits and neurogenerative effects, below.

A study on rats (Martin et al., 2012) used oral curcumin (0.7 g /kg twice a week) for 3 weeks, or equivalent curcumin dose in a WPE. Curcumin concentration in the liver and intestine were at least ten times greater with the WPE than curcumin, suggesting increased bioavailability.

An in-vitro human cell angiogenesis study (Liu et al., 2008) found that total inhibition of angiogenesis was achieved using a turmeric HSE which contained only 18.5µM curcumin concentration in comparison to a concentration of 120µM pure curcumin required for the same outcome. It was suggested that this 5 times effectiveness was due to other compounds.

In addition, a 15 μ M pure curcumin extract had no observed anti-angiogenic effect, however 9.3 μ M and 4.6 μ M curcumin in whole turmeric did inhibit angiogenesis. The fact that the inhibition was equal (77-78%) by both these preparations is particularly striking, suggesting that effectiveness was not proportional to concentration of curcumin in a whole plant extract, unlike results for the pure curcumin. Effectiveness may therefore not depend on curcumin concentration at lower curcumin concentrations in whole plant extracts. This may be of increased importance in a clinical setting as curcumin bioavailability is low and therefore action that is not dependent on this limiting factor may be preferable. The finding that more curcumin was detected in the aqueous solution obtained from the whole plant extract (0.29% w/w) compared to the solution derived from the pure curcumin preparation (which found non-detectable concentrations and no sign of biological activity), suggests that the whole turmeric extract increases solubility of curcumin in aqueous solution. This effect may be via non-polar compounds and support the need for fat soluble compounds to enhance bioavailability.

Cohly et al., (1998), in an in-vitro study found that equal concentrations of WPE turmeric and pure curcumin had equal antioxidant effects despite the much lower concentration of curcumin in the WPE. Furthermore the in-vitro study did not allow for the reduced bioavailability of curcumin compared to the WPE which would make the curcumin even less effective in oral dosing compared to the WPE.

Interestingly, curcumin was found to be mutagenic in vitro at concentrations of 10 μ g/ml whereas *C. longa* at 500 μ g/ml was not, even though it contains a higher dose of curcumin than 10 μ g (Araujo et al., 1999). Similarly, higher doses of curcumin in a rat diet increased rate of maturation of cataract, but not for *C. longa* dose with equivalent curcumin or lower doses of curcumin, showing that higher concentrations or doses are not necessarily more beneficial (Suryanarayana et al., 2003). Although evidence shows that curcumin is safe, even at high doses, this limited evidence suggests that the WPE form may offer additional benefits.

Evidence underlying the possible additional benefits of the WPE comes from studies considering the differences in constituents of the HSE and WPE. Unprocessed *C. longa* contains approximately 235 compounds, which, apart from the curcuminoids, may therefore be limited in the HSE which extracts curcumin preferentially (Aggarwal et al., 2013). Non-curcuminoid compounds in *C. longa* have been found in pre-clinical studies since the 1970s (Bone, 1991) to have potentially therapeutic effects. Nair et al., (2019) state that non-curcuminoids are 'equally potent as curcuminoids'. A review article (Aggarwal et al., 2013) investigated curcumin-free turmeric, discussing other compounds in turmeric that have anti-inflammatory, anti-diabetic and anti-cancer properties as well as other distinct properties to curcumin.

Bagad et al. (2013), found that the aqueous extract, volatile oil turmerones and curcuminoids all had comparable anti-inflammatory activity in vitro and turmerones were found to be neuroprotective (Hori et al., 2021; Lantz et al., 2005) and inhibited HIV (Cohly et al., 2003), as well as dose-dependently increasing proliferation of rat neural stem cells and injection of aromatic turmerone promoted neural stem cell differentiation in-vivo (Hucklenbroich et al., 2014). An aqueous *C. longa* extract administered in a RCT involving 48 participants found a positive effect on mood (Kawasaki et al., 2018). Other evidence includes a review (Aggarwal et al., 2013) of anticancer and anti-inflammatory activities of curcumin-free *C. longa* and other constituents (turmerin, turmerone, elemene, furanodiene, curdione, bisacurone, cyclocurcumin, calebin A, and germacrone). It is also noted that elemene is used as an anti-cancer treatment in China (Zhai et al., 2019).

Sprung (2016) offered some evidence concerning choice of preparation of *C. longa* from 2015 data. It was found that herbalists reported the strongest reasons for using both the HSE and WPE as effectiveness and convenience, suggesting that clinical evidence from practice was central to choice of preparation. Together with the finding of widespread use, this suggests that there may be a large body of clinical evidence from herbalists' practice to inform choice of preparation. This may be a valuable source of data, given that other evidence is limited. However there is currently a lack of facility for collating such evidence, which is complicated by the challenge of typical polypharmacy. It was also suggested supplement company seminars were influential on use of the HSE due to widespread use of the Lamberts Healthcare brand and widespread availability of their free seminars. However, at that time there was less choice of *C. longa* HSE products available than currently and they were 'novel' products. There was little overt evidence for other influences on choice of preparation such as use of research, herbal texts or influence of other herbalists. It is noted however that since this 2015 survey, the research body has increased greatly, although any influence on practice is unknown.

There is limited evidence to inform other issues such as side effects, bioavailability issues and natural variation (Bahl et al., 2014; Akbar et al., 2016). Although there may be concerns about side effects from *C. longa* HSE, as such a highly concentrated product, there is very little evidence of this being the case. For example Lao et al., 2006, investigating the safety of curcumin in humans, state '*The tolerance of curcumin in high single oral doses appears to be excellent*', and used up to an extremely high dose of 12g. However possible minor non-dose dependent gastrointestinal side effects were noted both in this study and also in Sharma et al. (2004). A recent review of *C. longa* HSE (Ahmad et al., 2020) concluded that it was safe even at 'extraordinary' doses (p.9) although noted interactions with some conventional medicine.

There are also some concerns about curcumin concerning the relationship between inhibition of drug metabolism enzymes, potential DNA impairment and iron chelation, although data is limited (Devassy, Nwachukwu & Jones, 2015).

3.2 *S. marianum*

The part of *S. marianum* used medicinally in WHM is the seed, which contains the major active constituents, known collectively as silymarin, a mixture of flavonolignans, mainly silibinin. Silymarin has been found to have potent antioxidant and hepatoprotective functions.

S. marianum is one of the oldest known herbal medicines, being used for over 2000 years as a herbal treatment in liver and biliary tract diseases (Schuppan et al., 1999; Sayin et al., 2016; Grieve, 1931; Luper, 1998; Culpeper, 1985). However it fell out of favour and nearly a century ago, Grieve (1931b) stated that it '*is chiefly used now for nursing mothers*'. This was followed by a re-adoption associated with HSE research evidence that started in the late 60's (Schuppan et al., 1999), showing hepatoprotective, antioxidant and anti-inflammatory effects in metabolic disease (Tajmohammadi et al., 2017). The German Commission E monograph, 1986 (Bisset & Witchl, 2001) and Bone (1991) recommended it for digestive disorders and liver damage, however Weiss (1991) wrote that '*milk thistle.....has largely been forgotten....(but) recent investigations have....shown it...in a completely new light*' (p.82) (it is proposed that this refers to specific research finding of potent hepatoprotective properties). After this, entries continued to be common (Hoffmann, 1996; German Commission E Monographs, 2000 (Blumenthal, 2000), Bisset and Witchl, 2001, Mills & Bone, 2003; Hoffmann 2003) and *S. marianum* continues to be included in all identified more recent herbal texts (Table 3.2), although there is no specific evidence for how widely it is used by herbalists.

S. marianum WPE contains 4-6% silymarin (Greenlee et al., 2007). A typical HSE tablet contains 80% silymarin. For example a 'Maximum strength milk thistle 300mg' tablet of 80% Silymarin HSE (Lamberts Healthcare Ltd., 2021b) is stated as containing 174mg of silymarin extracted from 8g of dried seed. Compared to this, the German Commission E Monographs (Blumenthal, 2000) recommend a higher daily dose of 12-15g of the WPE dried seed or 200-400mg of silymarin. Other texts (Table 3.2) vary in their recommended doses but most are higher than the Lamberts Healthcare HSE dose above. The HSE may therefore be viewed by some as a convenient way of administering a high 12-15g recommended dose of *S. marianum* seed.

The German Commission E monographs (Blumenthal, 2000) recommend *S. marianum* as the WPE and the HSE and other texts vary between listing the WPE only, the HSE only or both, reflecting historical use of the WPE and recent HSE research. However the frequent recommendation of large doses of the dried seed WPE that are similar in silymarin content to

HSE doses suggests a greater influence of research findings. Earlier writings (Grieve, 1931) recommended aqueous infusions which would have had very little silymarin present as it is not water soluble. Recommendations for both HSE and WPE therefore appear to be largely based on research evidence rather than traditional use.

S. marianum HSE RCTs on PubMed (Appendix 2) appear to have started in 2004; previous studies had been almost entirely pre-clinical and therefore less relevant to clinical practice. A search of '*S. marianum*' or 'silymarin' or 'silibinin' on PubMed gave 4580 results and with the 'human' and 'clinical trial' filters gave 123 articles, all of which concerned the HSE. There was no evidence found of clinical trials using the WPE. Although research evidence continues to increase, including RCTs, only limited systematic reviews and meta-analyses were found for 2020-2021 compared to *C. longa*. Although earlier conclusions were mixed (e.g. Abenavoli et al., 2018; De Avelar et al., 2017; Zhong et al., 2017), later reviews have been more positive. A systematic review and meta-analysis of *S. marianum* HSE in non-alcoholic fatty liver disease (Kalopitas et al., 2021) looked at 8 RCTs and found it significantly reduced transaminase enzymes (a measure of liver cell damage). Xiao et al., 2020 carried out a meta-analysis of 16 RCTs and found significant hypoglycaemic and lipid lowering effects. However, compared to *C. longa* HSE evidence is still limited.

There is some evidence of the potentially therapeutic effect of other non-silymarin constituents (Viktorova et al., 2019) that may be reduced or lacking in the HSE. No clinical studies were found that compared any other HSE herbs with the WPE directly. One pre-clinical study was found investigating an aqueous extract of milk thistle compared to silymarin finding it comparable in hepatoprotective properties to silymarin which is insoluble in water (Eldemerdash et al., 2016) and therefore not present in the aqueous extract. The significant hepatoprotective properties of the aqueous extract (containing constituents such as flavonoids) would presumably not be effective in a HSE 80% silymarin as their presence would be limited. As with *C. longa*, there is initial evidence that silymarin may have reduced bioavailability compared to the WPE (Javed et al., 2011; Parveen et al., 2011). There is also evidence for natural variation in *S. marianum* WPE which, unlike the HSE, is not controlled for (AbouZid et al., 2016; Martin et al., 2010; Shokrpour et al., 2008), although HSE preparations may also be subject to variation (Campodónico et al., 2001). In addition, although there is no evidence that processing negatively affects therapeutic properties of *S. marianum* HSE, Fisher (2009) notes the high extraction temperatures used for commercial HSE preparations. Finally, in terms of safety, like *C. longa* HSE, high doses of *S. marianum* HSE were found to be safe, with caution advised when used with narrow therapeutic window drugs (Soleimani, Delghandi, Moallem & Karimi, 2019).

3.3 *G. biloba*

The leaves of *G. biloba* are currently used medicinally in WHM and widely documented in *Materia Medica* (Table 3.2, p. 136), containing the active constituent terpenoids referred to as '*G. bilobalides*' and 'bilobalide'. These have been found to possess antioxidant, antiplatelet and cognition-enhancing properties.

There has not been a history of traditional use of the *G. biloba* leaf in any herbal tradition (Winston & Kuhn, 2008) and no mention is made in Grieve (1931), although the seed is used in TCM (Bartram 1998; van Beek & Montoro, 2009). Therefore, compared to other HSE with some element of traditional use, this herb is lacking documented evidence for use other than recent research on the HSE. *G. biloba* leaf is recorded widely in herbal texts from the 1980s onwards (Table 3.2) having been introduced in Germany in the 1960s (Drieu & Jaggy, 2000).

The most commonly and widely used HSE in the body of research is called EGb-761, containing 24% flavonol glycosides (quercetin, kaempferol and isorhamnetin or tamarixetin) and 6% terpene trilactones (*G. bilobalides* and bilobalide). This compares to at least 0.5% and 0.1% respectively in the dried leaf, which are variable over the year and environment (Guo, Wang, Fu, El-Kassaby & Wang, 2020; Lin et al., 2020). Since *G. biloba* HSE is not as highly standardised as the other HSEs considered here, meaning that guaranteed percentages of active constituents are far lower than other HSE considered here, it may be that it is considered to be more like the WPE, albeit a concentrated preparation, and this may encourage use. The HSE offers an element of certainty in terms of those measured constituents, however it is claimed that '*justification for the ...quantity of the ingredients in the extracts of the G. biloba leaves has never been published*' (Chan et al., 2007). A typical OTC HSE *G. biloba* preparation is made by Lamberts Healthcare (Lamberts Healthcare Ltd., 2021c) and a single 120mg tablet is stated as equivalent to 6g of dried *G. biloba* leaves. The German Commission E Monographs (Blumenthal, 2000) only recommend the HSE preparation, with no mention of the WPE, and the herb is referred to as '*G. biloba leaf extract*'. Other herbs are described by their names only. Other herbal texts (Table 3.2) all recommend the HSE where recommendations are stated, and where the WPE is mentioned the dose is generally large and 'equivalent' to the HSE dose. This may be less practical to administer, particularly in a herbal formula. This focus on the HSE is reinforced by statements in several texts. Kuhn & Winston (2008) state '*The tincture is significantly less effective than the standardised preparations and the tea has little or no activity*' (p.223) and Bartram (1988) stated of the WPE '*large doses may be required*' (p.199). Mills and Bone (2013) state that the WPE is not recommended because of uncertainty of constituent doses (due to variability over the year) and potential adverse reactions to *G.*

bilobalic acids (although this may be cautionary only as risks with oral administration are not clear (van Beek & Montoro, 2009)).

A search on PubMed of '*G. biloba*' or '*G. bilobalide*' or '*bilobalide*' with the 'human' and 'Randomised clinical trial' filters gave 327 results (see Table 3.1) which is a greater number than *C. longa*. This is surprising as the pre-clinical research body for *C. longa* is much larger with over 18 thousand results compared to about 4 thousand for *G. biloba* (Appendix 2). Unlike *C. longa*, however, there has not been a consistent increase in the rate of published RCTs since around 2012 and publishing rate of new RCT studies appears to be decreasing sharply (Appendix 1a), whereas RCTs for *C. longa* continue to rise exponentially. These findings are reflected in reviews of the literature which offer only limited support for clinical use. A recent brief review (Nguyen & Alzahrani, 2021) concluded that there was insufficient evidence for use of *G. biloba* HSE from RCTs on a wide range of health conditions. Chong et al., 2020 carried out a systematic review and meta-analysis of 12 RCTS in ischemic stroke and found '*limited evidence*' of benefit in quality of life, with injectable preparation more effective (injectable form was also found effective in vertebrobasilar insufficiency, a review by Cao et al., 2020). However, other reviews have been more positive and concluded the HSE may improve mild cognitive impairment (Liu et al., 2020; Kandiah et al, 2019) and retinal disease (Martinez-Solis et al., 2019). Ji et al. (2020) found improvement in neurological function in a systematic review and meta-analysis of 15 RCTs. Compared to *C. longa* specifically, conclusions from recent reviews suggest that evidence for use is limited. It is interesting that another recent review of 54 studies that found benefit of *G. biloba* HSE over a range of conditions related to oxidative stress was based on 51 pre-clinical studies rather than human RCTs (Achete de Souza et al., 2020). It may be that the strength of pre-clinical evidence outweighs the large volume of RCTs that followed. This may explain the relative reduced interest in research more recently, compared to other HSEs. Given the limited research evidence for *G. biloba* outlined above, the choice for herbalists may be whether to actually use the herb in practice or not. Unlike *C. longa* it is not known how widespread *G. biloba* use is by herbalists, whether WPE or HSE.

In terms of WPE studies, virtually all RCTs involved the HSE. The only evidence of any preparations of WPE *G. biloba* were 3 RCTs which used a fresh plant extract (Suter et al., 2011; Bäurle et al., 2009), but there was no recent evidence of any further studies using the WPE.

There is evidence that *G. biloba* HSE, Egb-761, may not contain the full range of constituents; specifically, *G. biloba* flavone aglycones, catechins, polyphenols and steroids may be lost in the production process (van Beek, 2002; van Beek & Montoro, 2009; Chan et al., 2007). Some of these already have interesting pharmacological properties in pre-clinical studies. For example

catechins and procyanidins were shown to inhibit beta amyloid aggregation and have antioxidant activity (Xie et al., 2014; Qa'dan et al., 2011) and biflavonoids were shown to reduce skin inflammation and adipogenesis (Lim et al., 2006; Cho et al., 2019). No pre-clinical studies were located that compared the HSE to the WPE or investigated the WPE.

A specific issue for *G. biloba* WPE is of natural variability of constituents related to harvesting time or growing location (Rimkiene et al., 2021; Kaur et al., 2012). Levels of the active constituents have been found to be highest in the autumn and this is considered the optimum time to pick the leaves. Although there have also been reports of preparation methods affecting constituent levels (Sati et al., 2013) this issue may affect most herbs. There have also been concerns about the nature of the extraction process of *G. biloba* HSE EgB-761 which requires 27 steps (Van Beek, 2002). Finally, a review of *G. biloba* HSE concluded that it is generally safe but with cautions concerning concurrent use with conventional medicine (Diamond & Bailey, 2013).

3.4 *S. serrulata*

The part of *S. serrulata* (Saw palmetto) used in WHM is the berry. Identified active constituents in recent research are the range of lipophilic compounds and modern research has focused on the use of *S. serrulata* in benign prostatic hypertrophy (BPH).

Unlike the herbs above, *S. serrulata* does have an uninterrupted traditional history of use in WHM. Traditional use records it being '*...used for many complaints which are accompanied by chronic catarrh*' (Grieve, 1931a) in the urinary and respiratory systems. Following modern research studies on use of the HSE in prostate health, it is mentioned for this use in Weiss (1988), Wren (1989), Bartram (1995), Hoffmann (1996), The British Herbal Pharmacopoeia, 1996 (BHMA, 1996) and The German Commission E monographs 2000 (Blumenthal 2000). There is no mention in Bisset and Witchl (2001). It is however recorded in all reviewed later texts (see Table 3.2, p.136).

A typical *S. serrulata* HSE such as Lamberts Healthcare 'Saw Palmetto Extract', a 160mg tablet, contains 85-95% lipophilic compounds, which represents an extract taken from 1.44g of dried berry (Lamberts Healthcare Ltd., 2021d). The whole dried berry in comparison contains about 9% lipophilic compounds (Talpur et al., 2003). Recommended daily doses of the WPE in herbal texts are mostly identified as between 1 and 3g daily but also as high as 6g, 3g being the equivalent of 2 Lamberts Healthcare tablets. Compared to the other HSE herbs reviewed here, the Lamberts Healthcare HSE does not offer a very high dose of the herb in a more convenient form than the WPE as the others HSEs discussed here, do.

Herbal texts mostly recommend both the HSE and the WPE at equivalent doses. These doses reflect the doses used in clinical trials, which are typically 320mg, equivalent to 2 Lamberts Healthcare tablets or about 3 g of dried berries. This dose may also reflect traditional use; Grieve (1931) recommends doses of up to 3.5ml of the herbal fluid extract, typically extracted from 3.5g of dried berries. Specific recommended use in prostate health in texts however, reflects the influence of research, rather than traditional use. A PubMed search for '*Serenoa serrulata*' with the 'human' and 'RCT' filter showed 72 results. There were no RCTs identified that used the WPE, all involved the HSE. In addition no pre-clinical studies that used the WPE were found. Looking at current research evidence supporting HSE use, a recent systemic review and meta-analysis looking at 4 RCTs of *S. serrulata* HSE (320mg per day for at least 6 months involving 1080 patients) compared to the medication Tamulosin for BPH found it comparable in measures of symptoms, quality of life and post-void residual volume (Cai et al., 2020). Another systematic review and meta-analysis of 27 RCTs and 12 observational studies (Vela-Navarrete et al., 2018), again with 320mg daily of *S. serrulata* HSE and 5800 patients showed significantly reduced nocturia and improved maximum urinary flow rate compared with placebo and similar improvement in symptoms to conventional medication (tamsulosin and 5-alpha reductase inhibitors). However, a more recent meta-analysis of 22 RCTs and 8564 patients (Russo et al, 2021) found no 'clinically meaningful improvement' in these scores apart from in longer term treatment of 12 months.

As for other herbs, there is limited evidence of the therapeutic benefit of compounds from *S. serrulata* other than the HSE lipophilic fraction. A chalconol glycoside, with antioxidant and antiproliferative effects (Abdel Bar, 2015) was identified and myristoleic acid was found to induce apoptosis in human prostate cancer cells (Iguchi et al., 2001).

Finally, regarding *S. serrulata* HSE commercial preparations, it has been found that differences in processing procedures may affect efficacy of the HSE (Ye et al., 2019) but that it has a good safety profile in RCTs (Novara et al., 2016).

Chapter 4: Summary, Aims and justification of the study

As discussed above, this study is important as it seeks to investigate issues of HSE and related modern research, which have a long history of controversy in parts of the WHM community. A description of WHM practice and the range of herbal preparations used, including HSE, have been outlined. The controversy of HSE and research have been explained and evidence for integration into WHM has been discussed, and although evidence so far suggests limited herbalist focus on research, use of HSE (specifically *C. longa*) may be widespread. Influences on choice of herb preparation, the choice between HSE and WPE, have been suggested and a wide range of evidence that may affect choice considered. It is not clear to what extent herbalists use HSE in practice or what the influences are for choices made, including how much research evidence is used. Finding out more about these specific questions will inform both herbalists' choices and the ongoing debate, but also others from the wider interested community, not only about HSE use but also how herbal professionals view them. With no satisfactory definition of WHM and varied approaches to practice within the herbal community, it is important to investigate the current state of attitudes towards these central issues, in order to inform interested parties, and also add to the understanding of WHM practice.

The aim of this study is therefore to carry out further research to expand on the initial evidence including the author's previous study, about use of HSE by herbalists. The specific stated aims of the study are as follows:

- Aim 1: To investigate the processes and pathways by which herbalists have come to use or not use HSE in their practice, which will include their attitudes and beliefs concerning HSE and published research.
- Aim 2: To investigate how widespread findings from interview data are, in terms of both herbalists and herbs used, therefore indicating to what extent practice has changed from the traditional approach.
- Aim 3: To promote discussion and education around choice of herbal preparation with those having an interest in providing herbal products, including herbalists, pharmacists, health shops and other health practitioners. Findings from this study will be used to inform both the practice of herbalists and herbal organisations, and more widely, those selling (or using) OTC HSE products, including pharmacists and other shops, and a wide range of health practitioners such as nutritional therapists and personal trainers.

Chapter 5: Methodology and Methods

5.1 Overview

The study involved Grounded Theory (GT) methodology with mixed methods research (MMR). Substantive theory about the topic of 'highly standardised extract' (HSE) use was built iteratively largely via interviews and a subsequent survey. GT with MMR has been described as '*particularly complementary*' (Howell Smith et al., 2020), to the extent that they have recently been more formally developed as Mixed Methods-Grounded Theory (Guetterman et al, 2019; Johnson et al., 2010; Howell Smith et al., 2020) or Mixed Grounded Theory (MGT) (Johnson & Walsh, 2019). The first part of the study consisted of individual interviews with herbalists, the data being analysed qualitatively. Interviews are the most common qualitative research method (King & Horrocks, 2010), qualitative research placing more emphasis on '*meaning, experiences and views*' (Pope & Mays, 1995, p.43). In this study it was important to use qualitative interviews to understand the processes behind use of HSEs; this was not considered possible using a quantitative approach alone. Themes identified from interview data concerning the first aim of the study, how herbalists have come to use HSEs, informed the development of an online, largely quantitative survey of the herbal community. This survey formed the second part of the study and data from these distinct sources of survey and interviews were integrated, together with existing literature, to further develop theory. This addressed aims one and two, understanding and quantifying HSE use.

The methodology and methods discussion starts with an explanation of the choice of GT methodology. These principles which were applied throughout the study and more fully explained throughout the chapter, as appropriate, in the discussion of the methods. The initial outline of the GT approach is followed by a discussion of the author's philosophical position towards the study, including reflexivity. Justification and explanation of the MMR approach is then discussed, followed by an outline of the interview and survey methods and integration of results. After this, ethical issues and dissemination of data are discussed.

5.2 The choice of GT approach

Grounded Theory was originally developed by Glaser & Strauss (1967) in the arena of healthcare, as a method of inductive theory development. This contrasts with the more common deductive methods at that time, where existing theory is tested. It is a very popular methodology in qualitative research (Pawluch & Neiterman 2010; Bryant & Charmaz, 2007). Although it has historically largely been associated with qualitative data, it can also include collection and analysis of quantitative data or a combination of both (Bryant et al., 2007; Mediani, 2017;

Johnson & Walsh, 2019) as used in this study. GT was considered most appropriate here as it is suited to areas where there is little or no existing research, where there is an opportunity for the development of new theory. It is particularly suited to small scale, exploratory, qualitative interview research that seeks to find explanations, rather than descriptions (Harris, 2015; Denscombe, 2014). The approach fits with the current study as it satisfies all these characteristics. There is virtually no pre-existing data on the processes by which herbalists come to use HSE and the aim of the study was to generate theory, understanding and explanation. It is considered suitable despite not being used in previous identified interview studies of herbalists (Nissen, 2010; 2015; Waddell, 2016) and was not as common as thematic analysis in a review of GP survey studies (Appendix 4).

There is no single agreed procedure for the conduct of GT research and it has diversified significantly since its original development (Maz, 2013; Denscombe, 2014). It may rather be considered inclusive of a 'family of methods' (Bryant et al., 2007). However, there are essential characteristics that remain constant and distinctive (Denscombe, 2014 p. 106). The key features of GT that set it apart from other methodological approaches include generation of theory that is 'grounded' in the data. Data collection is informed by ongoing analysis and categorisation of emerging data, even altering the original research question if indicated. Specific common characteristics include constant comparative analysis, theoretical sampling, and development of theory via theoretical saturation of categories (all three considered central by Hood, 2007), theoretical coding, theoretical sensitivity and memo writing (Willig, 2013; Lingard et al., 2008; Denscombe, 2014; Harris, 2015; Rose et al., 2015). Although different GT approaches have elements in common, the specific GT approach employed depends on many factors that are related to the researcher and the study (Chun Tie et al., 2019). In this study a classical Glaserian GT (CGGT) approach was employed. This approach is justified and explained below and throughout the outline of the specific interview and survey methods that follow.

5.3 Philosophical perspective, the author's background and reflexivity

It is important to reflexively consider the author's position in relation to the study to acknowledge their interaction with and influence upon data collection, analysis and conclusions. This is first discussed in terms of the author's philosophical perspective that informed the methodology, followed by personal background that may influence data collection and interpretation. After this the author's background knowledge of the topic is considered, a requirement of GT referred to as 'theoretical sensitivity'.

Identification of their philosophical perspective concerning ontological and epistemological assumptions enables the researcher to clarify their approach to the research process, the data, interpretation of findings and the nature of the relationship between the researcher and participants (Mills et al., 2006; Taghipour, 2014). The CGGT theory approach used here is based on a positivist realist ontology that assumes a 'real' world that is distinct from the observer and that epistemologically this can be objectively observed. This was the perspective that GT was first developed from, although there was little discussion of this in original texts (Bryant & Charmaz, 2007; Rieger, 2019). Glaser (2002) stated that CGGT '*makes the generated theory as objective as humanly possible*' (p. 5). It assumes that there is an objective truth that can be discovered by a neutral observer, who discovers pre-existing theory from collected data (Charmaz, 2001; Taghipour, 2014). This was developed by Glaser, a quantitative researcher (Stern, 2009), who argued that this was the pure form of GT (Rieger, 2019), and contrasts with Strauss and Corbin who stated that they did not believe in such a "pre-existing reality" (Mills et al., 2006), favouring a constructivist approach. The author aimed to 'extract' data about herbalists' attitudes towards HSE from interviews and survey, with a view to facilitating, but not influencing the provision of the data. However, despite having stated the aims of the research methodology being to find objective truth, the researcher was also aware that this is not ultimately defensible. It cannot be claimed either that data from participants is objectively 'true' in a positivist sense, or that the researcher has used an unbiased objective approach, taking rather a postpositivist critical realist ontological position. The recognition of these issues underly a spectrum of increasingly more constructivist GT methodologies (Rieger, 2019). However, despite these acknowledgements, these are not a reason to abandon the approach which is considered most appropriate for the research question in terms of an initial examination of the subject. The author therefore aspired to a more positivist approach with neutral influence in the interview data collection process, survey development and data analysis, but could not claim that this was completely achieved.

It was vital that the author was continually aware of their influence on the research process throughout the study. This was facilitated by memo-ing, a central method in GT for promoting reflexivity, and an important part of (but not exclusive to) this approach (Willig, 2013; Lempert, 2007; Pidgeon and Henwood, 1997). This involved documenting each stage of the study, offering details about how the researcher's attitude and understanding shaped the research and how this changed throughout. In line with GT, each memo was dated, with a suitable heading. They were initially recorded on an easily accessible mobile phone in the notes section. Examples of memos from the time of recruitment and interviews are transcribed in Appendix 5.

The author's initial position in relation to the study and the question of HSE is now considered as part of the ongoing practice of reflexivity (further discussion is located in the results section). The author, as a herbalist, shared a wide range of beliefs and knowledge with participants, and this was a benefit for accumulation of data. There were nevertheless differences between attitudes of the researcher and researched, and these are important to investigate in order to further understand their influence. The author's initial position was also affected by their background in studying chemistry, with an MSc in medicinal chemistry and virtually no knowledge of herbal medicine. The BSc in Herbal Medicine at the University of East London, attended by the author, was attractive as it included a 'scientific' approach to herbs. There was a strong focus on the chemistry of phytochemical constituents and an approach that reflected conventional healthcare theories. The author's initial approach to WHM was more akin to science-based 'phytotherapy' rather than that practiced from a base of TK. This initial scientific position was subsequently modified by training and experience in practice, leading to some conflict in the author's attitude towards HSE. Alongside an underlying affiliation with the natural presentation of WPE, as gained in training, sat the attraction of a convenient large dose of active constituent in these HSE herbs. Clinical evidence from the author's own practice in terms of HSE use has been inconclusive, with experience suggesting benefit from both HSE and WPE when directly compared. Conversations with other herbalists have not reduced this conflict and research evidence to inform the choice is limited. This uncertainty led to the previous study on *C. longa* (Sprung, 2016) given the lack of existing evidence for choice of preparation. Rather than offering clarity, it served to suggest an unexpected split in the WHM community, raising further questions, specifically those underlying processes by which herbalists have arrived at their decisions. The literature and evidence review, as outlined in the introduction, offered some additional data but did not increase clarity. The author therefore approached the current study having no clear judgement on the issue of preparation choice. Nevertheless, it was important that this attitude, which might challenge objectivity, was not communicated to interviewees.

In addition, reflecting the author's identified 'scientific' background, this may account for the appeal of the GT methodology, as a way of applying a more quantitative, structured approach to qualitative data (Johnson & Walsh, 2019), and specifically the classical Glaserian objective approach. The author had no prior experience or confidence in qualitative interviewing for research and this posed a risk of limiting the data from the interviews, both in terms of developing theory and informing the survey, but also in terms of accumulating rich qualitative data. In addition, the initial question that the author had concerning the topic of HSE use was focused on finding evidence for choice of preparation, rather than investigating wider practice, therefore it was important that the author did not limit their view of the topic, subsequent

findings and interpretation. Further detail about how the author's attitudes changed throughout the study, and may have impacted on findings, are included in the results and discussion section.

Having discussed the focus on objectivity and the influence of the author's attitude, this brings the discussion of methodology on to issues surrounding the author's knowledge concerning the topic. A specific challenge to avoiding bias in data collection and analysis is the requirement of the researcher to be fully aware of concepts and theories associated with the studied topic. This fundamental aspect of GT is known as 'theoretical sensitivity' whereby the researcher has an '*awareness of the subtleties of meaning of data*' (Strauss & Corbin, 1998, p. 41) and uses this knowledge to appropriately analyse the data and develop theory whilst being aware of the risk of personal bias being introduced (Glaser, 1978; Harris, 2015). Theoretical sensitivity arises from professional experience (the researcher has the advantage of being an herbalist), familiarity with the literature and immersion in the research process and data. Theoretical sensitivity was crucial here for understanding the qualitative interview and survey data in terms of intended meanings and examples of this are discussed later. In recognising that theoretical knowledge should not interfere with the emergence of theory in CGGT Holton (2007) and Lempert (2007) go as far as to state that the researcher should have carried out no extensive review of the literature or have pre-conceptions. This may allow theories to freely emerge from the data, with the researcher therefore having an open mind. However, Bryant et al. (2007) suggest that this proposal is only applicable to researchers with great experience in the wider field, with Stern (2007) and Timmermans & Tavory (2007) proposing that understanding of the research area is required to avoid confusion and conclusions born of ignorance, but that understanding should not define the research. Similarly, Gibson (2007) agrees that theoretical sensitivity of GT requires awareness of relevant literature, and Dey (1999) makes the point that an open mind does not mean an 'empty head'. The researcher did not have the option of a complete blank slate for this research topic and neither did they consider this desirable given the need for theoretical sensitivity in interpretation of the data outlined above. They also did not consider it a disadvantage to review the literature before the collection of data, believing this to contribute to theoretical sensitivity rather than risking increased bias. The author believed that an objectivist approach was necessary to obtain interview data that reflected the most important aspects of interviewees' attitudes towards the topic, rather than risking the emergence of more 'standardised' and less meaningful data from a more constructivist approach to interviews. Since this topic is well understood and long debated in WHM, herbalists are generally aware of the 'arguments' from both sides and minimal 'intervention' was considered necessary to avoid encouraging data that was more 'generalised' than specific to the individual participants.

5.4 Justification of Mixed Methods Research (MMR)

Before considering how the interview and survey stages of the study were carried out it is important to consider the reasons for using both these methods, in the form of MMR, or the more recently proposed MGT when considered in the context of using GT throughout the study (Johnson & Walsh, 2019). MMR may be described as the '*collection and integration of qualitative and quantitative data*' (Johnson & Walsh, 2019, p.521). It is suited to questions for which a solely quantitative or qualitative approach is not satisfactory for comprehensive insight or understanding of the topic investigated, and is an increasingly popular method in health research (Creswell & Plano Clark, 2018; Fletcher-Lartey et al., 2016; Johnson & Onwuegbuzie, 2004). The aims of this study, finding out about extent of use and reasons for use of HSE, required both an understanding of processes involved in HSE use, as outlined in Aim 1, and quantification in terms of the herbalist population, as outlined in Aim 2. The qualitative individual interviews with herbalists aimed to obtain in-depth data about the processes and influences by which they have come to use, or not use, HSE in their practice. This would not be as readily obtainable by a largely quantitative survey (Duane et al., 2016) which is also evidenced by the author's previous study (Sprung, 2016) where opportunities for more complex discussion in open-text boxes offered very limited information. Therefore, it seemed clear to the author that since this study focused on a similar participant body and topic, a more in-depth method was required to enhance understanding of herbal practice. In addition, the interview data was necessary to help develop initial theory that would inform the development of the mainly quantitative survey. The aim of the survey was to offer an element of quantification to that initial theory, and further develop it through integration of interview and survey data. Therefore, both approaches were needed and required the use of MMR.

Integration of qualitative and quantitative data is a fundamental part and key strength of MMR. It optimises strengths and weaknesses of each type of data, which, if successful offers a richer understanding. It is a challenging process and is most likely not to be fully achieved (Tunarosa & Glynn, 2017; O'Caithin et al., 2010). Integration is '*the intentional linking of qualitative and quantitative data with the goal of transforming the data,...a core feature of MMR and one of its key strengths...and can lead to innovative insights*' (Wu et al., 2019, p.909). MMR may consist of a range of designs. This study involved the popular 'exploratory sequential' design with the first qualitative interview stage exploring the topic and use of inductive analysis to inform new theory. This theory then informed the subsequent (mostly) quantitative survey stage (see Table 5.3, p 74 for details) which offered quantification and modification of the theory, effectively one form of data 'building' on another iteratively (Wu et al., 2019; Creswell & Plano Clark, 2018). It

was noted that the combination of GT and the exploratory sequential design MMR had been used previously, for instance by Ågerfalk & Fitzgerald (2008).

5.5 Stage one: Interviews

The account of the interview stage consists of the process by which participants were recruited, including the process of theoretical sampling. This is followed by the interview process and collection and analysis of data.

5.5.1 Recruitment of interview participants

Interviewees recruited were from the body of UK herbalists who were members of one or more of the five UK professional associations (PAs) for herbalists that appeared on a Google search for 'UK Herbalist association'. These PAs were:

- The National Association of Medical Herbalists (NIMH)
- The College of Practitioners of Phytotherapy (CPP)
- The Unified Register of Herbal Practitioners (URHP)
- The Association of Master Herbalists (AMH)
- The Association of Naturopathic Practitioners (ANP)

The author's previous study (Sprung, 2016) and all other identified UK online surveys of herbalists (Table 5.2, p. 70), surveyed only NIMH members. However, the current study included a wider range of PAs as they emphasise different aspects of practice. This is important for the in-depth investigation into attitudes towards practice. Surveyed practitioners were limited to members of herbalist professional bodies as the study is concerned with the state of professional practice only, with shared elements of education and codes of conduct.

Initial interview data was sought in a non-targeted way from the identified body of herbalists. Although this data would be used to inform the processes by which further interviewees were recruited, the initial approach was general and open to any volunteers. Requests for the first participants were first made via private Facebook groups for herbalists after obtaining permission from the group administrator. Use of Facebook is a widely used method in recruitment and may be a useful recruitment tool, although efficacy compared to other methods is still unclear (reviewed in Reagan et al., 2019 and Whitaker et al., 2017). Although no studies have been identified that used Facebook recruitment of herbalists requests on Facebook special interest groups for nurses, which is similar to this study, have been shown to be effective in recruitment (Desroches, 2020). The groups approached in this study were:

- Western Herbal Medicine Questions, for which membership is exclusively for qualified herbalists, with approximately 1000 members at the time of posting, and

- The National Institute of Medical Herbalists Members Forum, with over 200 members (of which the author is a member and therefore had access).

This method of recruitment was considered a suitable way of easily accessing a large number of herbalists. It assumed that the groups were actively used by members; the author had no reason to believe otherwise as they were observed to have several daily messages and associated discussions¹¹. Since the posts were made, Western Herbal Medicine Questions has moved platform and is no longer hosted by Facebook. It was not clear from which group responses came as messages from potential participants were sent to the author's email address.

It was noted that in a study of GPs (Ryves et al., 2016), unsolicited email recruitment was very limited, telephone contact was much more successful but best with contact from a local research network. More direct contact may therefore have been preferable, as found in other interview studies of herbalists (Gallo et al., 2014; Waddell, 2016) and healthcare professionals (Barnes & Butler, 2018). However, despite lack of direct evidence for recruitment of herbalists, the author expected that herbalists would readily offer to participate following these general requests on social media. This is despite the method being indirect, with personal experience of practitioners being very generous sharing practice both in individual meetings, group settings and online, and also following the high response to the author's previous study (Sprung, 2016). Altruism has been identified as the most important factor in research participation (Newington & Metcalfe, 2014). In addition, University of Central Lancashire affiliation stated on the online requests for participation (see Appendix 6) was considered (as found by Ryves et al., 2016) to support the recruitment process. Similar to survey response, more 'official' contact may lead to better recruitment (Mangione & Van Ness, 2009; Burns et al., 2008; Holyk, 2008).

Four volunteers who were members of a PA were recruited after several requests (Appendix 6). All potential interview participants who responded to requests were immediately sent emails (Appendix 7) consisting of a covering note, a detailed information sheet about the study and an electronic consent form to complete in and return (Appendix 7; all confirmed participants in the study returned the consent form).

In line with GT methodology, emerging themes from the initial coding of the first interviews were used to inform the recruitment of further participants, using 'theoretical sampling'. This is a fundamental part of GT, whereby the process of data accumulation is guided by the developing theory. Interviews were coded and analysed before the next interview, so that each one would

¹¹ The author calculated that there were approximately 6 comments daily on WHMQ given over 20,000 comments in 10 years

inform further interviews. The process of data analysis is more fully described later in the data analysis section.

Following open requests for participants having been relatively unsuccessful, this was not considered a suitable approach to continue with for further recruitment. Subsequent requests for participation were therefore more direct (as in Ryves et al., 2016) and individual contacts were made online, although further general requests on social media were also repeated. Ethics approval was granted for this change in approach.

In GT, as the researcher develops theories, these are tested by further cases. Possible variations concerning identified themes, that are not present in the data may become apparent. This may guide the data collection process to look for such 'missing' data or 'negative' cases that do not fit with a developing theory and may therefore develop theory further (Willig, 2013). Suggestions for who to contact next that emerged as 'missing' from the initial data were herbalists who use HE and those with busy practices. Suggestions were offered by the first four (and subsequent) interviewees. In addition, Facebook postings on Western Herbal Medicine Questions were also reviewed by searching for 'standardised extract' or 'curcumin' or 'silymarin' using the search function, in order to locate comments concerning HSE in general or specific common HSEs *C. longa* or *S. marianum*. Those herbalists identified by their comments on HSE were contacted via online messaging electronically to request an interview. Repeat requests for these direct messages were not sent if replies were not obtained, to avoid coercion.

As it was not known in advance how much data would be obtained or from where it would originate, it was not possible or desirable to predict or propose the required number or characteristics of herbalists to be interviewed. The sample size should be guided by the ongoing data analysis. The end point of data collection in GT is that suitable numbers and characteristics of participants are included to the point of 'theoretical saturation' of the data, '*when additional analysis no longer contributes to discovering anything new about a category*' (Strauss, 1987, p21). The researcher should see repetitive data at this point (Bloor & Wood, 2006). This is the full version of GT, as opposed to the abbreviated version that collects all the data before analysing it and therefore does not allow for theoretical sampling (Willig, 2001). A risk of the GT approach is that themes may not emerge from the data. This was not considered a significant risk, with the author's experience of conversations about HSE use within the community of herbalists, and willingness to share understandings. In total 13 interviews were carried out and provided a wide range of data which was considered to be sufficient to cover the major themes of this topic and represent theoretical saturation. The researcher believed that unexplored major themes, based on the author's theoretical sensitivity, were not likely to be revealed by

further interviews. The theoretical saturation in the interview stage was not negated by the further accumulation of data in the subsequent survey stage, this being considered a different form of data that was not obtainable from interviews. In the recent interview study by Waddell (2016) 13 herbalists were also interviewed, however other GT interview studies and mixed-methods studies of CAM practitioners were identified and used between 19-27 interviews (Wiese & Oster, 2010; Grace et al., 2008; Roberts et al., 2020).

5.5.2 The process of data collection in the interviews

The interviews were all individual and carried out remotely, either online or by telephone. Individual interviews suited the nature of herbal practice, with herbalists typically working alone, and the sensitivity of the topic favouring a non-group setting (which was an issue confirmed by Hvidt et al., 2016). In addition, location in relation to the author prevented in person interviews. Interviews were recorded on a password protected mobile phone and private computer for back-up.

King & Horrocks (2010) outlined interview requirements for obtaining high quality in-depth explanatory data. An interview ideally aims to build rapport (King & Horrocks, 2010) and this was supported by the researcher being a herbalist and having that in common with the participants. During the interview process, one to two minutes was spent at the beginning in general chat to put the interviewee at their ease, hopefully reducing inhibitions and enhancing rapport. The interviewee was then asked the main question about how they came to use HSE, or not, in practice, the interviewer being clear about the definition of HSE in the study. Largely open interviews satisfied the requirement (King & Horrocks, 2010), that they allow for a wide range of data by being open-ended and flexible. It was important to avoid leading questions and this was managed by being limited to the main research question and the option of supporting questions. These questions expanded on the main question in a general open-ended non-specific way without making assumptions about the topic (Appendix 10). Although Halton (2007) suggests that only open interviewing is appropriate for CGGT to avoid imposing the researcher's assumptions on the data and this was recognised as a risk, the author felt more confident in the use of semi-structured interviews, to allow for potential prompting of participants if/when required. As predicted however, there was little need for the support questions. The main question prompted interviewees to talk about their views at length, with little input from the researcher. In practice, the interviews were considered to be effectively open. Input into the interview from the researcher, after posing the initial question, was limited to reflecting and clarifying what was said by the interviewees; the lack of use of support questions was seen as positive in terms of objectivity. It avoided imposing additional influence on the interview data

collection, other than that which was freely given by interviewees. In addition, the author was careful to avoid any language or tone of voice that might communicate bias (King & Horrocks, 2010). Care was taken to ensure clear understanding of data from the interviewees and clarifications of statements were reflected back to participants as the author believed was appropriate. It was also important to avoid any power imbalance between interviewer and interviewee and care was taken to avoid any suggestion of judgement given the potentially controversial nature of the topic.

At the end of the interview, interviewees were asked whether they gave their consent to be contacted again if any further data was required as the theory developed, as per the information sheet, and if so, their preferred form of contact. All gave consent however no further contact was made, apart from sending a summary of the analysis of all interview results for comment. No further comments were offered by interviewees regarding results data when sent out.

5.5.3 Data analysis

Recorded data was transcribed verbatim by the author directly after each interview. The audio recording was immediately and permanently deleted from both the mobile phone and private computer sites.

NVivo software was used to organise and analyse data on an ongoing basis from the first interview onwards and facilitate coding, according to CCGT (Flick, 2018; Rieger, 2019) as outlined here. Analysis and theory development was started with substantive 'open coding'. Each section of interview that was considered to represent an individual 'comment' was assigned a relevant title and entered onto the NVivo file, coding being either 'in vivo' reflecting the wording in the comment or 'analytic', more explanatory of the comment's content, as appropriate. According to GT 'constant comparative analysis' was carried out, involving familiarisation through reading, re-reading and comparing the data as it was collected and organised. This is an important feature of CCGT as it helps to increase objectivism and reduce bias that stems from immersion in the data (Rieger, 2019). Initial coding prompted the development of theory as selective coding focused on identification of analytical categories that related to the central 'core' category of 'influences on HSE use', with no limit on the number of categories. As many codes as were required by the data were created and reflected as much detail in the data as possible. Lack of time was not a limiting factor for the author (Willig, 2001). Further development of higher level analytic categories from grouping codes together were facilitated using 'theoretical coding', via 'coding families' (Table 5.1, p. 67). Coding families detail a list of general concepts that are generally applicable to a research question. They may be used

to prompt the researcher to find ways in which the data may be coded and integrated but without 'forcing' theory from the data, rather allowing theory to emerge, as claimed by Glaser (1978) (Kelle, 2007; Rieger, 2019). CGGT as adapted by Bohm (2004) was adopted (see Table 5.1) as it is the least prescriptive, offering support in developing categories without risking invalid associations in the data, thereby supporting objectivity. Examples of how the coding categories might relate to the topic of HSEs have been suggested in Table 5.1. For instance, examples of 'causes' of HSE use could include recommendations from various sources and 'context' could include use in certain conditions. The 'theoretical sensitivity' of the researcher was crucial here as analysis moved from descriptive categories to more analytical levels as theory developed. Constant comparative analysis was carried out throughout the study, with data including existing research, referred to as the use of 'emergent fit' in the process of CGGT iterative theory development (Rieger, 2019).

Table 5.1: Coding Families (Bohm 2004) and examples of how they may be related to the current study

Coding Families	Concepts	Examples in the context of the study
The 6 Cs	Causes	...of HSE/WPE use – e.g recommendation from herbal training courses, seminars, texts, other herbalists; use of research; ease of use
	Contextssurrounding HSE/WPE use – serious illness, strong medicine needed, individual context of patient, availability, cost, convenience
	Contingenciesfuture possible use of HSE or not
	Consequencesof seminars, training, comparing HSE to WPE, clinical evidence
	Conditions	e.g. patient request, limited use
Process	Stages, phases, phasings, transitions, passages, careers, chains, sequences	Clinical experience, influence of other herbalists, changing attitude over years

The degree family	Extent, level, intensity, range, amount, continuum, statistical average, standard deviation	Extent of HSE use, how many and how often, how readily are they used
Type family	Types, classes, genres, prototypes, styles, kinds	Different HSEs
The Strategy Family	Strategies, tactics, techniques, mechanisms, management	How herbalists decide on the choice of HSE/WPE
Interactive Family	Interaction, mutual effects, interdependence, reciprocity, symmetries, rituals	Influence of other herbalists and organisations
Identity-Self Family	Identity, self-image, self-concept, self-evaluation, social worth, transformations of self	How herbalists identify themselves in relation to HSE use, as a controversial topic.
Cutting-Point Family	Boundary, critical juncture, cutting point, turning point, tolerance levels, point of no return	When herbalists decide to use HSE or WPE
Cultural Family	Social norms, social values, social beliefs	About HSE and WPE use in the herbal community
Consensus Family	Contracts, agreements, definitions of the situation, uniformity, conformity, conflict	Conflict or sensitivity of the topic, effect of different herbal training courses,

5.6 Stage two: Survey

The second stage of the study was a largely quantitatively analysed online survey. This is discussed below, with explanation of the development and implementation. The aim of the survey was to further develop substantive theory from the interview stage through analysis and integration of both sources of data. The survey stage may be considered to be an abbreviated version of GT, with all data collected before analysis and no opportunity for theoretical sampling

or theoretical saturation (Willig, 2001). Other aspects of GT were still continued in terms of constant comparative analysis, memo-ing, theoretical coding and theoretical sensitivity.

It is of central importance that survey data is reliable and valid, which in turn is related to the nature of the survey itself and the response rate. Consideration of factors that influence the potential response rate must be deliberated in tandem with development of survey structure and content. In the following, initial considerations for response rate are introduced, which concern the choice of online method, the importance of topic relevance and the choice of anonymous survey. This is followed by an account of how the survey was constructed to achieve the aims of the study, as informed by interview data and other literature. Support materials are then considered, followed by an account of piloting, the survey launch, data collection and analysis. Finally, ethical issues are considered.

5.6.1 Survey development and structure, including maximising response rate

The explanation of the development of the survey starts with a specific consideration of response rate, followed by detail of how the survey was constructed.

Designing a survey to maximise the response rate is of fundamental importance. A high response rate not only increases data collection and perceived quality of the study, but also low response rate is an important source of bias which challenges validity (Mangione & Van Ness, 2009; Burns et al., 2008; VanGeest, 2007; VanGeest et al., 2007; Thorpe et al., 2009). Given the limited number of potential participants, maximising response rate is of additional importance here.

Initial background information for informing the issue of response rate in the development of the survey was sought before the survey was constructed, including identified surveys of herbalists (Table 5.2; Appendix 11). Influences on response rate concerning the general approach to the survey, before construction commenced, were the choice of online or postal, the issue of anonymity, and the presentation of the topic itself which are discussed below. Further considerations related to response rate are interwoven throughout the description of survey development in the sections below.

Table 5.2: Response rates of identified online surveys of herbalists

Postal Studies:

Study	Survey Design	Recruitment of practitioners	Response rate
Barnes & Ernst	Postal survey	All practicing members of the NIMH (n = 317)	19.6% (n = 62)
Casey, Adams and Sibbritt, 2007; 2008	Postal survey. Distributed with NHAA professional journal over 2 issues.	All full members of the National Herbalists' Association of Australia (NHAA) (n=649)	58.2% (n=378)
Nissen, 2010	Anonymous, postal survey. 31 closed and open-ended questions, 4 pages	Sample of NIMH practitioners (5 regions); unclear how practitioners identified (n=188)	29% (n=55)
Frost et al., 2014	2-sided A4 survey; all close-ended questions. Follow-up surveys sent to non-responders.	All UK members of NIMH, CPP and AMH with viable practice addresses (n=598)	40% (n=239)

Online studies

Study	Survey Design	Recruitment of practitioners	Response rate
Brock et al., 2014	Email survey, with 2 follow-ups, oral alert at NIMH conference and advert in NIMH newsletter. Mostly open-ended questions	All members of NIMH with identifiable email addresses. (n=377)	16% (n=62)
Rooney & Pendry, 2014	Brief online survey, 11 open and closed questions via www.surveygizmo.com	email contacts on NIMH register (n=428)	17% (n=72)
Corp & Pendry, 2013	Short survey, 10 closed, 1 open and 2 mixed questions. Surveys were sent via www.surveygizmo.com and via post with prepaid return	NIMH register, email contact with link to online survey (n=470); further contacted by post (n=61). total (n=531)	26.7% (n=142)
NIMH, 2021c (unpublished)	Short online 11 point survey, with closed questions and open comment box at the end via SurveyMonkey	561 NIMH members surveyed	18% (n=98)
NIMH, 2021d (unpublished)	27 point survey consisting of closed questions and open comment box at the end via SurveyMonkey	653 NIMH members, present, past and student	32% (n=206)

Considering the choice of an online survey, the general benefits are that they are quicker, more cost-effective and they offer in-built data analysis tools (Gill et al., 2013; Trobia, 2008). Nevertheless, before taking the decision about use of online or paper survey, evidence from the above surveys of herbalists in Table 5.2 (p. 70) was reviewed. This review of similar survey evidence is considered a necessary requirement for successful survey development (Trobia, 2008). Although historically there have been lower responses to online surveys, a recent survey carried out in 2019 by the NIMH (2021d) (not published in a peer reviewed journal) had a far higher response rate than other online surveys with a similar population and method. This finding, together with other benefits of online surveys, were considered sufficient evidence to justify this choice, particularly since the 2019 NIMH study was so recent. In addition, the author believed that the high response rate from their previous survey on a related topic and population suggested a likely high response in the present study (Sprung, 2016). Even without the encouraging response in NIMH (2021d) and the presumed popularity of the topic, it was predicted that the response to the online survey would be at least as high as online surveys sent to similar herbalist populations, the lowest of which was 16%. The survey was launched on 16th March 2020 just before COVID lockdown restrictions were imposed on the 23rd. This may have been of benefit for survey responses in terms of herbalists spending more time at home and having time to engage with the internet, although this is not clear. However use of an online survey may risk a response bias through those who do not participate in 'modern' online technologies being unlikely to respond.

The perceived value of the study is also important for response rate (VanGeest et al., 2007). Barnes & Ernst (1998) studied practising NIMH members (n = 317) using a postal survey and the overall low response rate of 19.6% (particularly low for a postal survey) was at least partly due to the nature of the questions. Many herbalists wrote to say that requesting specific herbs for conditions did not fit the holistic way they practised. In addition, a much lower response rate was achieved in the 2018 NIMH (2021c) study compared to NIMH (2021d) with the major difference between them being the subject matter. The 2019 study concerned the annual conference which may have been more popular than the 2018 topic of non-herbal business issues. It was therefore important, before constructing the survey that the author was careful to avoid alienation of participants by making assumptions about practice in both the survey and supporting materials. It was also important to be being mindful of wording to make the topic as appealing as possible.

Considering the choice of an anonymous survey, a large volume of evidence associates increased high rates with surveys that are explicit about confidentiality (Mangione & Van Ness, 2009). Reassurance of anonymity and confidentiality was offered here. Although studies do not find an

advantage over anonymous surveys compared to declarations of confidentiality (Mangione & Van Ness, 2009; Leonhard et al., 1997), the potentially sensitive nature of the topic here is considered important enough to choose an anonymous presentation for a profession with such small numbers, in order to support response rate and honesty of answers.

The survey was constructed via the Jisc onlinesurveys software (onlinesurveys.co.uk) and informed by interview data and evidence from the literature. Details of the survey are shown in Appendix 12¹².

The development of survey content was informed by themes that emerged from analysis of interview data, also taking into account the central questions of the study, and optimised through reference to relevant literature. A summary of how interview themes informed the survey is found in Table 5.3 below and more detail in Appendix 13.

¹² It is not possible to show in this version the programmed rules that regulated the completion of the survey and reduced the possibility of confusion.

Table 5.3: Themes emerging, summary of data and how this informed development of the questionnaire (see Appendix 12, p. 243 for details of questions).

Themes			
	Summary of data from those not using HSE in practice	Summary of data from those using HSE in practice	Question in survey that investigates themes further (open comments in Question 28 may offer data on any themes)
Influences on use of HSE or WPE			
Reports of clinical evidence for use of HSE or WPE from herbalists' own practice	<p>Evidence from own clinical practice and comparison between HSE and WPE leads to WPE use</p> <p>Unexpected clinical evidence that WPE performed better than HSE</p> <p>Insufficient clinical evidence of additional benefit of HSE / have no need for HSE</p>	<p>HSE are found to be very effective</p> <p>HSE more effective when compared directly to WPE</p>	<p>Reasons given for non-HSE use, Question 3 (an open question asking about why herbalists do not use HSE in practice and this gave opportunity for wide ranging answers that may include the many themes that emerged from interview data).</p> <p>Influences on HSE use, Question 7 (this was a structured question, offering options, to obtain clear evidence for HSE use which otherwise may have been limited; this is reflected in the limited amount of interview data concerning HSE use).</p> <p>Have herbalists compared HSE to WPE in practice, Questions 14 to 17</p>

Influence of other herbalists on use of HSE or WPE	<p>Influence of respected herbalist or herbalist seminar</p>	<p>Initially was influenced by other practitioners who treated cancer</p>	<p>Reasons given for non-HSE use, Question 3</p> <p>Influences on HSE use, Question 7</p>
Attitudes towards supplement companies that supply HSE	<p>Supplement companies that sell HSE are primarily financially motivated (therefore use of product is questionable)</p> <p>Used Lamberts Healthcare curcumin HSE but stopped due to 'company ethics'</p>		<p>Reasons given for non-HSE use, Question 3</p> <p>Influences on HSE use, Question 7</p>
Influence of Research on HSE or WPE use	<p>Read research supporting WPE compared to HSE</p> <p>Insufficient research evidence to support use of HSE</p> <p>Research conflicting</p> <p>More likely to follow other herbalists and (materia medica) books than research</p>	<p><i>G. biloba</i> HSE is recommended in NHS guidelines</p> <p>Research evidence is available, therefore we should follow it</p> <p>Need to interpret research carefully as much is not relevant to practice</p> <p>Some may use research on HSEs to justify use of WPE; if you follow research that involves HSE, use HSE to replicate study</p> <p>research evidence is available, therefore we should follow it</p>	<p>Reasons given for non-HSE use, Question 3</p> <p>Influences on HSE use, Question 7</p> <p>Questions about training in research skills, usefulness of research training, frequency of use of research and most useful research, Questions 9 to 12</p>
Reasons for use of HSE or not			

<p>HSE stronger or bigger dose</p>	<p>Issues around large doses involved in HSE / may be too strong</p> <p>I don't use HSE as don't treat serious illness</p>	<p>Use HSE if needed to work quickly (e.g. cancer); HSE may be 'stronger' and quicker acting</p> <p>Use HSE if want a big dose. I use large doses of herbs</p>	<p>Reasons given for non-HSE use, Question 3</p> <p>Reasons for HSE use, Question 8. As with Question 7 this question was structured to guarantee data responses.</p> <p>Reasons for most likely HSE use, Question 22, open text answers</p>
<p>HSE useful for specific or serious illness</p>	<p>HSEs appropriate for specific disease process HSEs aren't stronger or more effective, just more specific in application. HSEs are appropriate in certain instances</p>	<p>I do a lot of cancer support; HSEs may be appropriate when illness is serious</p>	<p>Reasons for HSE use, Question 8</p> <p>Reasons for most likely HSE use, Question 22</p>
<p>Practical approach to HSE use</p>		<p>Use in medical setting where they are accepted</p> <p>Use them as they'll only be used by pharmacists etc</p> <p>Herbalists are best qualified to use them</p> <p>Alternative to alcohol</p> <p>HSE may be a current trend</p> <p>Most herbalists don't practice very much</p>	<p>Reasons for use of most likely HSE, Question 22</p>

Underlying attitudes			
<p>Focus on the 'non-scientific' natural balance</p>	<p>Belief that natural plant is better / lack of synergy with HSE / natural complexity is important</p> <p>I don't have evidence for my beliefs – it's instinctive, very little evidence for views.</p> <p>Belief in loss of synergy with HSE is not based on evidence.</p> <p>Make it up as...go along</p> <p>I have a non-scientific approach</p> <p>Herbal practice is a mix of art and science and the science is limited</p> <p>Not how I want to practice; choose not to use them; it doesn't interest me</p> <p>HSE are more like pharmaceuticals or 'products'</p>	<p>I believe synergy is probably still there with HSE</p> <p>HSE is preferable to pharmaceutical option;</p>	<p>Reasons given for non-HSE use, Question 3</p> <p>Reasons for most likely used HSE, Question 22</p>
<p>Complex, unclear and controversial</p>	<p>Very complex issue and not clear</p>	<p>The findings will be interesting, useful</p> <p>Not entirely sure why I use HSEs</p> <p>Herbalists don't like to admit working in a non-traditional way</p>	<p>Q13 asked about clarity surrounding the choice between HSE and WPE since interview data suggests the issue is considered complex.</p>

	<p>Making a decision about what to use is complicated</p> <p>Unsure about my position</p> <p>feelings are mixed</p> <p>I give patients options because I'm not sure of the best option</p> <p>Not sure how I feel about them – not convinced</p> <p>It's a controversial issue</p> <p>Glad you're doing it (the study)</p>	<p>We all want to have a discussion about it</p>	<p>Question 27 asked about how useful herbalists believed this study is.</p> <p>No direct questions in the survey addressed controversy. The anonymous nature of the questionnaire may encourage honest answers for this controversial issue</p>
<p>Open minded</p>	<p>Open to the idea</p> <p>I would want to be convinced they offered additional benefit compared to WPE</p> <p>Would use HSE if WPE doesn't work</p> <p>respect the use of HSE; I recognise their value but hand over to other practitioners</p>	<p>Flexibility in approach</p> <p>I've changed my mind about certain supplements in the past; changed mind, used to be wary, not now</p>	<p>Questions 20 to 22 assessed open-mindedness, asking about most likely use of HSE including those herbalists who do not report use of HSE.</p>

<p>Examples of other factors that may affect choice of preparation</p>	<p>Environmental/sustainability factors in HSE production</p> <p>HSE are expensive</p> <p>Patient preference for WPE / natural products</p> <p>I think herbalists use HSE for random reasons</p>	<p>Certain plants need to be standardised to bring active constituents up to a high enough level</p> <p>Inconsistency of WPE</p> <p>Patients like them</p> <p>Extra boost, additional support</p> <p>Don't want to miss out on the benefits of HSE</p> <p>Use evidence on an individual herb basis</p>	<p>Reasons given for non-HSE use, Question 3</p> <p>Reasons for most likely HSE, Question 20 to 22</p>
<p>Historical use of HSE</p>	<p>Used to use them</p>		<p>Questions 4 and 5 asked about historical use of HSE by non-HSE users</p>

It was important that the survey questions addressed the aims of the study. Most questions in the survey addressed Aims 1 and 2 (understanding how herbalists have come to use HSE or not in practice and quantification of these findings). All the questions informed Aim 3 (promotion of discussion around this topic). See Table 5.4 (p. 81).

Table 5.4: List of questions in the survey and how they were used to address the aims of the study, how herbalists have come to use HSE, quantification and informing the debate (see Appendix 12 for full survey questions).

Question number of survey	Question as stated in the survey	How the question informs the aims of the study: understanding HSE use, quantification and informing the debate
1	Consent	NA
2	Do you currently use any highly standardised herbal extracts in practice?	Quantification of HSE use in the herbalist community
3	Please give reason/s for not using standardised extracts	Understanding how herbalists have come to not use HSE and quantification of reasons
4	Even though you don't currently use standardised extracts in your practice, have you done so in the past?	Quantification of historical HSE use and contributing to understanding of how this has changed
5	Please specify which standardised extract/s you used to use in practice.	Quantification of type of HSE used in the past and understanding how this has changed
6	Please specify which standardised extract/s you currently use in practice.	Quantification of types of HSE used and contributing to understanding of how this has changed
7	Please select the importance of the influences below on your decision to use standardised extract/s	Understanding and quantifying influences on decision to use HSE in practice
8	Why do you use standardised extracts in your practice?	Understanding and quantifying clinical reasons for use of HSE in practice
9	Have you been trained in analysis of peer-reviewed research articles published in journals?	Understanding the influence of research on choice of HSE or WPE and quantification
10	Was this on a formal training course or was it as part of CPD?	
10 b	Have you found this training useful in your clinical practice?	
11	Approximately how often do you access peer reviewed research articles published in journals as part of your professional practice or ongoing CPD?	
12	Do you follow the result of these studies by using the standardised	

	extract as specified in the studies or do you substitute the whole plant (or whole plant extract) for the same indications?	
12 b	For use of which plant medicine in your practice have you found modern research evidence most useful?	
13	Are you unsure and lacking clarity about whether to choose a standardised extract or a whole plant medicine?	Understanding and quantifying attitudes towards HSE or WPE
14 to 17	Have you ever directly compared a whole plant (or whole plant extract) to a standardised extract in your practice	Understanding and quantifying influence of clinical evidence from practice
	Which products did you compare?	
	For each trial of comparison in your practice, which product/s did you find more useful?	
	Can you give any details of how it was more useful?	
18	Have you ever noted unwanted side effects from use of a standardised extract?	Understanding and quantifying the influence of side effects associated with HSE use
19	Please give details of the product and the unwanted side effect/s	
19 a	Did you submit a Yellow Card detailing the side-effects	
20	Can you think of the most likely situation where you would use a standardised extract, even if you haven't yet done so and it is purely theoretical?	Quantifying open-mindedness to use of HSE in practice
21	Please give the identity of the standardised extract	Quantifying potential use of specific HSE
22	Please indicate why you would choose that product in the given situation or condition	Understanding and quantifying reasons for use of HSE by both HSE users and non-HSE users
23	Approximately how many patients do you have contact with per week?	Understanding and quantifying relationship between characteristics of herbalists and HSE use
24	Where did you undertake your training as an herbalist?	
25	In which decade did you qualify as an herbalist?	

26	What professional body are you a member of?	
27	Do you think it is useful to find out about UK herbalists' use of standardised extracts?	Whether herbalists believe the study to be useful will inform the debate.
28	Do you have any further comments about use, or not, of standardised extracts in your herbal practice?	General information that is important to herbalists that may inform understanding

Now moving on to consider other details of survey question development, a 'respondent friendly' approach was employed for survey construction. This is part of the 'Tailored Design Method' (TDM), considered a standard for mail survey design (Thorpe et al., 2009)), as used in the author's previous survey and relevant aspects were applied here. A 'respondent friendly' approach aims to achieve clarity of questions which are non-judgemental, unbiased, with no potential confusion or conflict in response, simple, clear instructions, logical, flowing question structure, clear, appealing appearance and formatting, good legibility and avoiding unnecessary questions (Burgess, 2001; Trobia, 2008; Wolf, 2008; Holyk, 2008; Mangione & Van Ness, 2009; Burns et al., 2008; VanGeest et al., 2007).

Considering question structure, they were mostly closed-ended and quantitative, which are frequently used in survey research (Trobia, 2008) and most were limited to 20 words per question stem (Burns et al., 2008) being less cognitively demanding of participants (Holyk, 2008). Care was taken to make optional answers mutually exclusive and exhaustive (Fowler & Cosenza, 2009; Burns et al., 2008).

It is not clear from previous herbalist online surveys what effect the choice of open or closed questions has on response rate. For some online studies employing open-ended questions response rate was low (Brock et al., 2014, Rooney & Pendry, 2014), whereas studies with higher response rates had mainly closed questions (Corp & Pendry, 2013; NIMH, 2021d). However the response to NIMH (2021c) which included closed questions was low whereas a postal survey (Casey, Adams & Sibritt, 2007; 2008), with open ended demanding questions, had a very high response rate compared to similar others with closed questions. Conclusions are therefore not straightforward. There is probably a balance to be struck between response rate and perceived complexity of the survey; a mix of mostly closed-ended, with limited or optional open-ended questions was considered a sensible option here.

The author's previous survey (Sprung, 2016) was relatively simple and undemanding and this may have been a major factor in the high response rate. One participant indicated that they appreciated the simplicity. Open-text boxes allowed for additional data without imposing

complexity on the survey. This would appear to be an efficient way of obtaining more complex qualitative data but little additional information was actually provided in these text boxes. Despite this, open-text boxes were retained in this study and considered a necessity here with lack of existing data on the subject. These opportunities not only allow for unanticipated answers but may also modify the balance of power between participants and researcher which may increase response rate (Burns et al., 2008).

Question order has been found to improve data quality starting with simple or general questions, moving to more demanding questions and questions of a sensitive nature and finishing with demographic questions (Trobia, 2008; Burns et al., 2008). This order was adopted for this survey, the author's previous one and by Frost et al.'s (2014) study which achieved a high response rate. As with the author's previous survey it was important that neutral language was used for this potentially controversial topic; particular attention was paid to avoiding any indication of bias from the author.

5.6.1.1 Supporting documents

Supporting documents such as the request for participation (Appendix 6) and information sheet (Appendix 12) are an important part of a survey package. Efforts were taken to ensure that all support materials used neutral language to avoid alienating herbalists who might think the study did not apply to their practice.

The quality of contact information is important for response rate (Gallagher, 2008) however in online surveys this may be complicated; some studies indicate that most participants exit at the point of reading the introductory information. Although it may be best to keep introductory information as brief as possible for this reason (Toepoel, 2017) this was not possible here. Considerable information was required in the introductory sheet concerning ethical issues and clarification of the requirements of the study.

The online initial invitation to participate (Appendix 8) was designed according to Toepoel's (2017) recommendations – '*intriguing, simple, friendly, trustworthy, motivating, interesting, informative, and above all else short*' (p. 17). In addition it made the most of the existing relationship of the author with the herbalist population and making a request for 'help'. However, the effect of the content of the invitation is likely to be related mainly to the topic and population (Toepoel, 2017) and following the author's previous successful survey (Sprung, 2016) the author had confidence that response would be favourable. The introduction was similar to the contact letter sent in the previous study. It was kept short and contained only necessary information, about the researcher, the topic, with a reassurance of confidentiality and with contact details of the researcher and supervisor (VanGeest et al., 2007). It included reference to

The University of Central Lancashire to reinforce university affiliation which has been shown to promote response rate if the institution is respected (Mangione & Van Ness, 2009; Burns et al., 2008; Holyk, 2008). University or PA affiliation has been associated with higher response rates in some herbalist postal surveys (Casey et al., 2007; 2008; Frost et al., 2014) and also in GP surveys when associated with a representative association (Owen et al., 2019). This association was not clear in herbalist online surveys (Appendix 11).

The information sheet (see Appendix 12, as part of the survey), with more necessary detail, was accessed by clicking on the online link. It gave further information about the study, including background, the researcher and supervisors, aims, university and course details, anonymity and confidentiality.

A deadline of 4 weeks was included in the information, although deadlines have not been shown to increase response rates (Mangione & Van Ness, 2009). Also included was an estimate of how long it would likely take to complete the survey and the importance of herbalist participation for its success. It was hoped that a reference to the valuable results of the previous study would encourage participation as the perceived value of the study is important for response rate (VanGeest, Johnson & Welch, 2007). Thanks for participation was included at the end of the information sheet which is reported to increase reported enjoyment (Holyk, 2008). Participants were also asked to send an email the author's UCLan email if they required a summary of the findings.

5.6.1.2 Piloting

The final process before launch of the survey was piloting, a necessary requirement (Trobia, 2008). Piloting was carried out by 6 herbalists to detect variance, flaws or obvious bias in questions, or answer options that may have affected reliability and validity of data. All herbalists carrying out the pilot completed it successfully and no suggestions were made for modification. The survey was therefore considered to have face validity.

5.6.2 Recruitment and data collection

The survey was sent to UK herbalists who were members of the five identified UK PAs, the same population pool as the interviews. PAs were requested to send the online link for the survey out directly to practising UK members, the PA origin adding weight to the study. This is reflected in the high response rates from the most recent NIMH (2021d) online survey, compared to unsolicited emails in other studies of a similar population (Appendix 11 / Table 5.2, p. 70). PAs were contacted to request distribution of the electronic survey link to their UK members who practice WHM and all PAs agreed (Appendix 9) to distribute the survey with the covering note

in the PA electronic newsletters (e.g. Appendix 8). A request was sent to PAs to repeat the online survey link to members after 4 weeks.

Reminders may be the most important technique for increasing response rates (Mangione & Van Ness, 2009). This is confirmed by many studies (e.g. Burns et al., 2008; Toepoel, 2017) including the author's previous study, and reminders play a crucial part in the TDM (Thorpe et al., 2009) where the first reminder typically increases the first set of replies by 50%, then halving this return each successive time over 4 postal follow-ups. The author's previous study strongly supported the benefit of a follow-up email as about 50% of responses arrived after this reminder. The online link was repeated from PAs in the subsequent newsletter (the item was placed in a more prominent position in the 2nd NIMH newsletter posting) and 3 further times on Facebook forums (Appendix 6). When no additional responses were obtained from further posting, the survey was closed to new entries on the onlinesurveys website. The survey was open in total for 4 months.

5.7 Ethical issues

Ethical approval for this study was obtained from the University of Central Lancashire College of Health Peer Review Panel (STEMH 947). The study was carried out in accordance with UCLan *Code of Conduct and ethical principles for research* (UCLan, 2021a;b).

5.7.1 Informed consent

Informed consent was considered to have been given for interview participation through emailing the information sheet and consent forms to interviewees. Informed consent was indicated by return of the electronic consent form, agreeing to the terms of participation according to the information sheet. For the survey, consent was understood to have been given by ticking the required consent box to confirm that the participant agreed with the terms of participation explained in the information sheet on the first page of the survey. This consent box represented question one of the survey (Appendix 12, p.245).

5.7.2 Data analysis and integration of interview and survey data

Data analysis was facilitated by the survey software (Jisc, 2021), enabling easy manipulation. Quantitative analysis did not include inferential tests but cross tabulations were explored, and qualitative data was integrated with findings from the interviews.

Interviews and survey initially provided distinct collections of largely separately analysed data, by use of qualitative and quantitative methods. Interview data consisted of in-depth qualitative data, coded into themes or theories about HSE use as detailed above. Survey data was largely quantitative and was analysed in line with these identified themes, to further develop theory. Qualitative data from the survey was incorporated into the interview data as appropriate. The

two bodies of data were readily integrated as the interview findings informed the survey, therefore most themes were relevant to both. The integration of both types of data informed the developing theory in different ways. Survey data offered further development of theory from interview findings, including through an element of quantification. Comparing and contrasting interview and survey data provided further insights. Integrated data is presented in the results section and explained under appropriate headings, closely related, although not identical to, the emergent themes from interview data. Development of the theory outlined in the results continued in the discussion section to ultimately build an explanatory picture of HSE use in the herbal community. The author believed that theoretical saturation had been achieved in terms of what was discoverable via the interviews but this cannot be claimed for the survey as the author could not steer the recruitment. The type of integration of qualitative and quantitative data used here, as MMR, may be described as ‘merging data’ via a ‘narrative, weaving’ approach (Wu et al., 2019; Cresswell & Plano Clark, 2018; Fetters et al., 2013). During the analysis and presentation of the results, data was re-visited as necessary, in line with the constant comparative analysis of the GT approach. This helped to ensure that it was appropriately situated in the ‘narrative’ of the results and developing theory. Data was moved and further split as needed, the original themes being used as a flexible base for the final results narrative.

5.7.3 Anonymity and data protection

For the interview stage, no identifying details were requested or included in the transcription notes; the notes were identified by a number, which were linked to the participant’s contact details on a separate document. The Interviewees were made aware that data would be presented and discussed in the study in a way that avoids the use of identifiable personal details and therefore minimises the chance of individual identification. Risk of identification was highest with certain interviewees being well known in the community and having run seminars. To ensure that all interviewees were happy with the documented results, each interviewee was provided with a draft copy of the data presentation to allow any changes to be made that they may not have been happy with. There were no objections received.

The possibility of individual identification from the survey was minimised by being anonymous and limiting personal questions that might risk individual identification. Any potentially identifying details were not used in the report. The information sheets asked participants not to include identifying details. The option to request a summary of findings was via direct email to the researcher rather than linking an email to the participant survey data.

If participants inadvertently gave responses in interviews or survey which included potentially identifiable information, it was anonymised appropriately. However, with a limited number of

herbalists in the UK there is still a small risk of this happening, particularly if individual's personal expressions of opinion are recognisable.

Considering data protection, data obtained was kept confidential, being accessible to the researcher and supervisor only and original interview recordings were deleted after transcription. In line with UCLan policy, raw data and consent forms are stored securely on UCLan servers for 5 years and then destroyed.

Should evidence have emerged of potential unsafe practice by herbalists during the data-gathering, the intention was to ask the interviewee about whether they considered their practice unsafe and what informed their conclusion. Advice would be sought from the author's professional body, whilst maintaining anonymity of the participant/s, and that advice used as a basis for a further conversation with the participant. This was considered an unlikely outcome given the low risks associated with herbal practice in the UK. This is evidenced in part at least by the low cost of insurance cover and lack of recorded serious adverse reactions to herbal medicines when prescribed by professional herbalists. Therefore, this unlikely eventuality was not included in information provided to potential interviewees as it was considered an unnecessary additional burden of information and practitioners already being governed by codes of conduct.

5.7.4 Participant inconvenience

The time demands of completing the survey were considered minimal compared to the possible benefits of informing herbal practice. The personal inconvenience to participants of the interview stage was greater, given the demands on their time and the information sheet stated that there was no minimum time requirement.

5.8 Dissemination

Finally, in terms of data dissemination, a summary of the study findings will be sent directly to emails of participants who requested them, as advised on the information sheet. Furthermore, the author plans to publish these findings in a peer-reviewed publication, the Journal of Herbal Medicine, which is available online via Science Direct and share at future professional gatherings of herbalists.

Chapter 6: Integrated results of interviews and survey

Interview and survey data, collected according to Classical Glaserian Grounded Theory (CGGT) in order to build theory, are presented here according to the emerging themes relating to 'highly standardised extracts' (HSEs). They address the first two aims of the study, investigating how herbalists have come to use HSEs and offering quantification of this in the herbal community. Interview data consisted of in-depth qualitative data, coded into themes or theories about HSE use, as per CGGT. Survey data was largely quantitative and both sets of data were integrated and reported here. This highlighted how the two forms of data compared and contrasted with each other to further inform the developing theory.

The results below offer an account which shows a wealth of information about HSE use and the factors underlying it. Results are presented, first with findings concerning response rate and reported interest in the study. This is followed by quantification of HSE use and specific HSE herbs used, and then results concerning how herbalists have come to use HSEs or not. Finally there is a discussion of reflexivity. Quantitative findings are presented as whole integer percentages, rounded up or down to the nearest number and are percentages of the total 78 responses unless stated otherwise. Further data for survey questions is located in Appendix 14, under the survey question number.

6.1 Response rate and reported interest in the study

Response rate was limited throughout the study. Initial requests for interview participants on social media (Appendix 6) yielded 4 volunteer interviewees, with no HSE users amongst them (from here onwards individual interviewees will be specified by the prefix No. followed by their assigned number). No. 7 suggested that this may be because '*people don't want to admit to working in a non-traditional way*' and this is discussed later in the issue of HSE controversy. There is also evidence it was not clear to potential participants whether they were 'suitable' to participate. No. 5 reported: '*I must admit I did read your thing and I did think I don't know if I'm what you're looking for so it may be that that's what people have thought*'. Subsequent focused requests were more successful; of 18 direct requests made via online messaging of HSE users and busy practitioners, 9 replied and consented to participate in interviews.

The thirteen interviews offered a large volume of data about HSE or 'whole plant extract' (WPE) use, with an equal representation from those using HSE and those who did not (see Table 6.1 below). Analysis of data from the interviews was considered to represent theoretical saturation and there was no evidence of 'missing' categories.

Table 6.1 : Showing interviewee order, identification as referred to in the study, and whether they reported use of HSE or not *

No. order and identification	Herbalists who reported use of HSE	Herbalists who reported not using HSE
No. 1		X
No. 2		X
No. 3		X
No. 4		X
No. 5	X	
No. 6	X	
No. 7	X	
No. 8		X
No. 9		X
No. 10	X	
No. 11	X	
No. 12	X	
No. 13		X

* A recurring finding throughout presentation of the results here was differences between findings from HSE users in interviews and HSE users in the survey. HSE users in interviews were found to be more 'positive' about HSE and research than in the survey; this is proposed to be due to interviewees being more experienced in HSE use and therefore more 'identifiable' for recruitment purposes (through recommendations from other herbalists and comments made on social media); this is indicated in the results as appropriate.

In total, 78 responses were received to the online survey. Of these, 30 replies were received after the first PA newsletter posting, the rest after repeat posts via newsletter and Facebook, which were stopped after 3 posts as no more responses were being received (see Appendix 6 for details of the repeat postings).

The response rate for the 78 replies was not obvious as the surveys were not sent by the author directly to individual herbalists. Numbers of practicing herbalists reached by the online link had to be estimated. This was achieved through accessing online practitioner listings of the PAs on their 'find a practitioner' pages, taken at the time of sending the survey link. This was considered a reasonably accurate method of calculating the number of practicing herbalists in the surveyed PAs who are those likely to be able to share data about practice. Response rates ranged from 19 % (NIMH) to 7 % (AMH), with a weighted average of 16 % (see Table 6.2, below). ANP (Association of Naturopathic Practitioners) figures were not included in the calculation as there were no responses from members. It was not clear if the survey link was sent as there were online communication difficulties.

Table 6.2: Percentage response rate for PAs, estimated using numbers of practicing herbalists listed on 'find a practitioner' pages on PA websites **

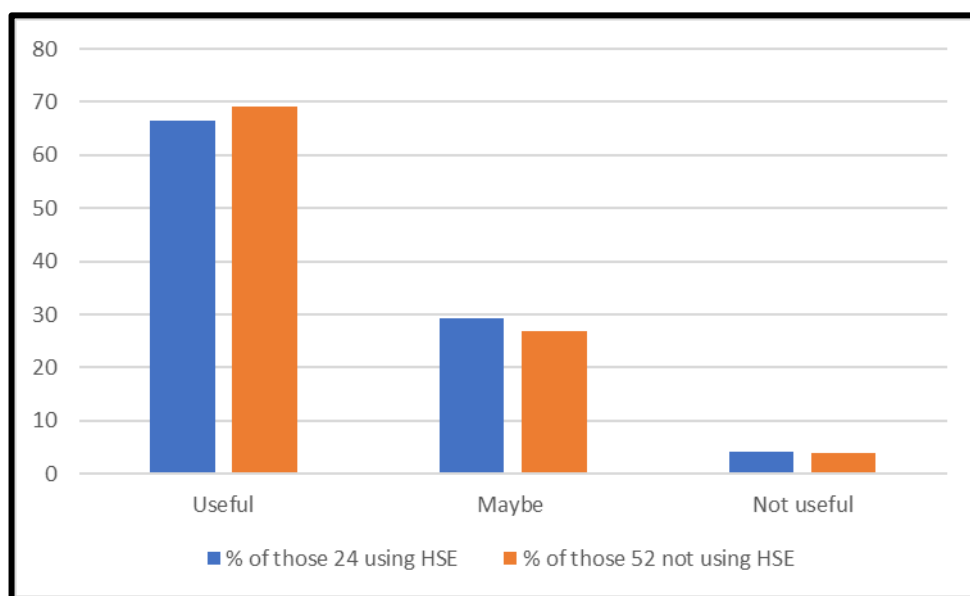
Professional Association	NIMH	CPP	URHP	AMH	AVERAGE (weighted) RESPONSE RATE
Number of replies*	56	18	7	5	
Estimate of herbalists surveyed	300	112	48	74	
% response rate	19 %	16 %	15 %	7 %	16 %

*13 herbalists reported belonging to more than one PA, 4 did not state PA

**It is recognised that official figures of all PA members are likely to be much higher as they include non-practicing members, student members and retired herbalists. For example Mills & Budd (2000) identified 966 UK herbalists and NIMH (2021d) surveyed 653 members. However for the purposes of this study, responses are only requested from herbalists concerning issues related to clinical practice and therefore an estimate based on online listing is considered an adequate estimate of numbers.

Reported interest in the study was high. Although only those who found the topic interesting were likely to complete the survey, the author has only had positive feedback from herbalists in general about researching the topic. Survey data showed general positivity towards this topic of this study with 68 % (n = 52 out of 76) reporting that they thought it was useful; 28 % (n = 21) said 'maybe' and only 4 % (n = 3) said 'no'. Interviewees only expressed interest, below, with no statements that were not in favour. There was also little difference in opinions between those who use HSE and do not use HSE (see Figure 6.1 below).

Figure 6.1: Chart to show how useful 76 HSE users and non-users report finding the research question (Question 27, see Appendix 12, p.250).



No. 11 stated:

'I'm glad that you're doing it...it's a mine of information'

No. 8:

'I think the thing is that I just don't know the answer to these questions....which is why you need to be asking them and why it's a really good thing to ask...and I think it's a discussion we all need to have, and I and [other named herbalists] are really interested in this, we all really want to have a discussion about it'

6.2 Quantification of HSE use and HSE herbs used

Considering quantification of HSE use, current use is first detailed, with details of specific HSE herbs used.

As a simple quantification of HSE use, of the 78 online survey participants, the population was split into 69 % (n = 54) 'non-HSE users' who reported no use of HSEs in practice and a large

minority of 31 % (n = 24) 'HSE users' who reported HSE use in Question 2 (as defined in the introductory section of the survey, see Appendix 12, p.246).

Moving on to a consideration of the specific HSE herbs used, to begin with, findings concerning the issue of HSE definition will be reported, followed by use of the specific HSE herbs. HSE definition was an important issue to be aware of throughout the study. During analysis of the surveys, care was taken to only consider data that referred to HSE products as defined in the study (Appendix 12, p. 245), rather than those that are less highly standardised (often tincture) WPEs with measured constituents. There was some limited evidence of confusion about the definition of HSE used in this study, but also evidence that the HSE definition was largely understood, as evidenced below:

Although all those who stated that they use HSE in Question 2 (Appendix 12, p. 246) gave at least 1 example of an HSE as defined in this study, as required, 4 herbalists also gave examples in Question 2 of other HSE extracts not defined as HSE here¹³, that is products that do not contain very highly elevated percentages of active constituents. These examples were not included in the study analysis and subsequent responses were assumed to apply to the HSE/s of interest stated.

In Question 21 (Appendix 12, p.250) where an example of the most likely used HSE was given, only 1 herbalist stated an extract not defined as HSE here as their only example (St John's Wort, *Hypericum perforatum*) and data associated with this answer this was omitted from the analysis.

The appropriate focus (outlined above) on only the limited range of HSE products (n = 8) in Question 2 (Appendix 12, p. 246) and Question 21 (Appendix 12, p.250) (n = 6) contrasts with the wide range of herbs (n = 26) stated in Question 12 (Appendix 12, p. 248) about useful herbal research in general, showing appropriate herb references in terms of question requirements.

There was also some evidence of confusion in Question 4 and Question 5 (Appendix 12, p. 246), which asked about previous use of HSE, and 9 % (n = 5 of 54 non-HSE users) gave examples of less standardised HSEs that do not meet the criteria in this study¹⁴. These results were not considered further and limited confusion about the HSE definition was not considered to invalidate comments about HSE.

It has also been assumed from the data that if a product is mentioned that is commonly available as an HSE, as defined here, then if an herbalist stated that they use the HSE of that

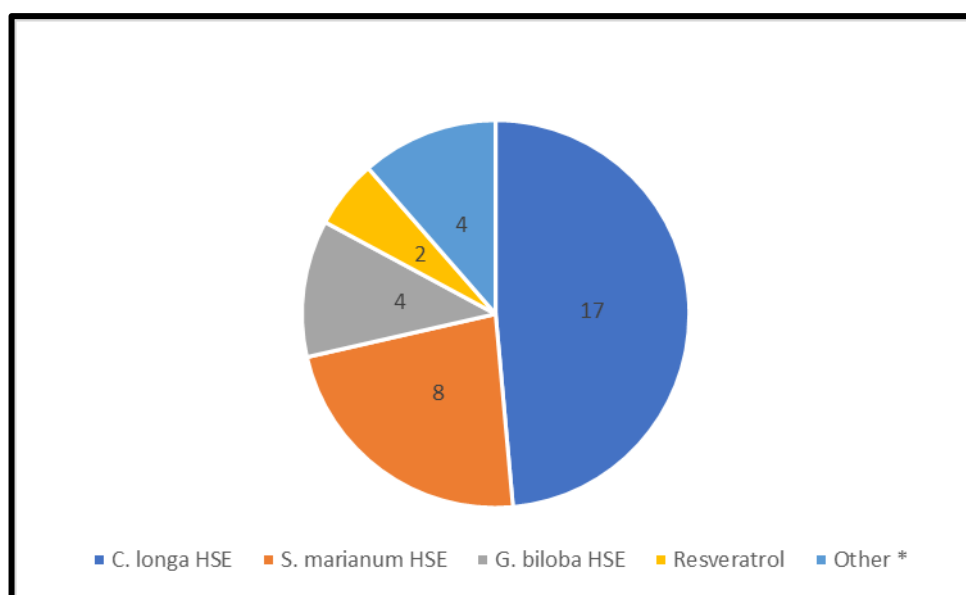
¹³ These herbs were *Echinacea Spp.* (1), *H. perforatum* (2), *Rosmarinus officinalis* (1) and *Rhodiola rosea* (1)

¹⁴ These herbs were *Echinacea Spp.* (1), *H. perforatum* (2), '*Asparagus racemosus*' (1), *G. biloba* WPE (1), *Salix alba* (1)

plant they are identifying the HSE rather than any other product that does not satisfy the HSE definition. This is particularly an issue for *G. biloba* which is available as a tableted HSE and also a liquid, less highly standardised HSE which would not satisfy this the definition for this study. Since there was relatively little evidence of confusion amongst herbalists in the data it is assumed that the preparations of *G. biloba* stated satisfy the definition.

The 24 herbalists who reported using HSE gave 36 total mentions of specific HSEs that were used in practice in Question 6 (Appendix 12, p. 246), with *C. longa* by far the most popular HSE (see Figure 6.2, below). It was reported to be used by 71 % (n = 17) of 24 HSE users and it is 49 % of total HSE mentions from current HSE users. It was mentioned by over twice as many HSE users as the next most popular HSE, *S. marianum* (n = 8), followed by *G. biloba* with n = 4 mentions. A specific result related to the author’s previous study on *C. longa* amongst NIMH members is that 25% of NIMH members in this current study reported use of *C. longa* HSE (including in this figure one herbalist who reported use of ‘lots’ of HSE).

Figure 6.2: Chart to show frequency of mention of individual HSEs by the 24 HSE users (Question 6, Appendix 12, p.246)**



* ‘Other’ = *Boswellia serrata*, *S. serrulata*, green tea, cordyceps/coriolus, all mentioned once each. Resveratrol is included as an HSE as it is usually highly standardised *Polygonum cuspidatum* (Japanese Knotweed).

**9 herbalists (38 % of 24) stated 2 or more HSE. In addition to the HSEs stated above 4 herbalists also stated products that are not considered to be HSEs in this study (specific herbs stated were *H. perforatum* (2), *R. officinalis* (1), *Rhodiola rosea* (1), *Echinacea* spp. (1), *Allium sativum* (garlic) (1))

C. longa HSE was still by far the most popular HSE in the wider ‘open-minded’ responding population who can ‘imagine’ a use for HSE. This data comes from the ‘most likely HSE’ that would be considered even if none were actually used in practice (Appendix 14, Question 21).

6.3 Understanding how herbalists have come to use HSE or not

A major part of the study is investigating the influences and reasons that have led to choice of HSE or WPE, which are now considered. The results presented below offer a picture of how herbalists have come to make decisions about choice of preparation. This section starts with the identified limited positivity towards HSE, despite widespread use, and a strong central focus on the natural WPE. There is evidence that some herbalists may not have persisted with HSE use. Despite these findings, other factors were found that support use of HSE. There was little evidence for strong feeling against HSE or of historical controversy, with widespread open-mindedness to use. Despite lack of strong feelings towards HSE, a central split was identified in the community between those who were open-minded to HSE use or not and reported clarity of preparation choice was high. Widespread use of HSE was reported as based largely on research evidence (the general use of research is also presented) and evidence of 'strong' characteristics from practice, as well as the influence of other herbalists.

6.3.1 Limited 'positivity' towards HSE and strong focus on the 'natural' WPE.

A central finding in the study was the limited positivity identified towards HSE, despite widespread use, and a strong focus on the use of the 'natural' WPE. Although this preferential affiliation with traditional WPE is to be expected, data concerning choice of WPE was particularly strongly focused on this issue. Results concerning these findings are presented below.

Despite widespread use of HSEs in the herbal community, there was limited 'positivity' identified towards them in terms of how many were reported to be used in practice. Only a small minority of herbalists, who reported use of more than one in practice, were considered to be most positive about HSE use. Use of more than one suggested that herbalists had a positive attitude towards HSEs in general rather than finding a use for one specific preparation. Others either used HSEs in a more limited way or did not use them at all. Survey data showed that the majority, 71 % (n = 17) of HSE users reported use of only one HSE. The remaining 29 % of HSE users (n = 7 or 9 % of total responses) reported use of 2 or more HSE herbs in Question 6 (Appendix 12, p. 246), specifically *C. longa*, *S. marianum*, *G. biloba* or *S. serrulata*. The question specifically asked for all HSE, therefore it is assumed that respondents reported all individual HSE herbs used in practice. Only a small minority of responding herbalists in the survey were therefore considered 'positive' about HSEs, using this measure. In addition there were no statements offered in the survey that related to more than occasional use. Such comments concerning frequency of use were limited to: '*Generally, I do not use them.....(I) occasionally use standardised extracts*' and '*I usually avoid standardised extracts*'.

In addition, since reported HSE use largely concerned *C. longa* this also supports the theory that herbalists are not positive about HSEs in general but rather this specific HSE.

In interviews there were a limited range of comments relating to extent of use, both in terms of frequent or only occasional use. This ranged from No. 11 and 9 reporting a lot of use to No.6 and 10 each reporting use of only 1 SE. Greater reported use of HSEs in interviews was considered to represent the experienced HSE users reflect the small minority of more 'positive' herbalists in survey responses and who were more readily identified for interviewing on the topic.

Following this identified general limited positivity to HSEs, this contrasts with the related strong focus on the 'natural' WPE. The overwhelming reason for not using HSEs was strongly stated as representing a traditional approach to practice that focuses on the 'natural' balance of constituents as discussed in the introduction. Several references were made in the data to 'synergy'. This focus was particularly strongly represented in the survey, with the overwhelming nature of most comments across questions being based on a traditional, natural approach to herbs (Table 6.3, p. 97). This included optional open comments (Table 6.5, p. 99), which offered more evidence of the strength of feeling about WPE use since there was no overt requirement for these comments.

Reasons for not using HSE were given in Question 3 (see Appendix 12, p. 246), by 53 out of 54 non-HSE users (1 gave no reason). Of these, 77 % (n = 41 of 53 responses) stated their preference for using the WPE in its 'natural' state and 91 % gave reasons generally indicating a preference for the traditional WHM approach (See Table 6.3 below and Appendix 14, Question 3 for more detail). Common wording included 'natural', 'constituent balance' (used by n = 19; 36 % of 53 responses) and 'synergy' (by n = 5; 9.4 %) and ideas expressed were very similar to each other. As detailed in Table 6.3 there were responses from a very small minority (9 %, n = 5) of 53 non-SE users who reported *only* reasons other than this preference for the natural WPE and traditional approach (see 'Other reasons not specific to HSE'). Three of these 5 reported that they could imagine using an HSE in Question 20 (Appendix 12, p. 249) and are therefore considered more likely to be more open-minded about HSE use.

Table 6.3: Summary of reasons given for not using HSE (Question 3, Appendix 12, p. 246)

Reason given for not using HSE (more than one reason may have been given by individuals)	Number of herbalists mentioning reason / % of 53 responding
Reasons that reflect the traditional 'natural' WHM approach	
Prefer WPE because of natural balance of constituents	41 / 77 %
Prefer WPE (with no explanation)	7 / 13 %
HSEs are 'pseudo-drugs', more like conventional medicine	5 / 9 %
Prefer traditional evidence	1 / 2 %
Side effects / safety of non-traditional preparations	3 / 6 %
Other reasons related to HSE/WPE	
HSE are expensive	4 / 8 %
More research needed	3 / 6 %
HSE are 'commercialised'	1 / 2 %
Not required	3 / 6 %
WPE more effective	1 / 12 %
Other reasons not specific to HSE	
Used in the past	1 / 2 %
Limited practice	1 / 2 %
Habit	1 / 2 %
I don't have strong views	1 / 2 %
Suppliers do not stock them	1 / 2 %

Other evidence for the strong focus on the natural WPE compared to HSE came from Question 28 (Appendix 12, p. 250), open comments. Since open comments were optional they may offer insight into what participants wished to share as particularly important. Comments supported the theory above of a strong focus on the WPE and little positivity towards the HSE (see Tables 6.4 and 6.5, below). In total 33 (42 %) of the 78 questionnaire responders made comments that were related to the topic, with non-HSE users being much more likely to offer comments. Of 54 non-HSE users, 48 % (n = 26) made comments compared to only 29 % (n = 7) of the 24 HSE users. Non-HSE users were more likely to make positive comments about their choice, with 42 % (n = 11) of 26 non-HSE users' comments referring to the 'natural' balance of WPE, and 73 % (n = 19) of comments were considered to be directly 'pro-WPE'. In contrast, none of the 7 HSE users were considered to have made any overtly 'positive' comments about their

choice. Furthermore only 3 of 7 comments made by HSE users were considered to be mildly 'pro-HSE', with 4 actually in favour of WPE use. These optional comments showed commitment to the traditional WPE approach as a matter of conscious principle (indeed only one survey respondent indicated that WPE were used out of 'habit' or lack of thought).

Table 6.4 : Comments made by HSE users in 'open comments' (Question 28, Appendix 12, p. 250).

Question 28: Comments by n = 7 HSE users	Number of herbalists (comments)
Comments in favour of HSE use	3 'they have a role to play'; 'I was taught..(HSE are)...useful for specific conditions'; 'I used to be wary of extracts but not so much now...(after a)...seminar on cancer treatment....a useful addition to practice'
Comments in favour of WPE use	4 'generally I do not use them', 'I usually avoid HSEs', 'mostly use WPE', 'WPE milder, safer, wider range of therapeutic actions'

Table 6.5 : Comments made by non-HSE users in ‘open comments’ (Question 28, Appendix 12, p. 250).

Q.28: 29 Comments by 26 non-HSE users (3 herbalists (Nos. 2, 3 and 4) made a second comment in addition to comment 1)	Number of herbalists commenting / % of 26	11 herbalists who consider HSE use in Q.20 / % of 11	15 herbalists not considering HSE use in Q.20 / % of 15
1. Comment about natural balance of constituents in WPE *	11 / 42 %	4 / 36 %	7 / 47 %
2. HSEs similar to pharmaceutical drugs *	6 / 23 %	0	6 /
3. More information on the topic will be useful	7 / 27 %	7 /	0
4. Open-minded	2	1	1
5. Safety issues with HSE *	1	0	1
6. Issues are ‘remote from practice’ *	1	0	1
7. Use HSE on self only	1	0	1

*. These comments are considered to be ‘pro-WPE’

The range of reasons given for not using HSEs in the survey were limited and focused on this one aspect of practice. The open text box for the question asking about reasons for not using HSEs did not limit response, specifically asked for multiple reasons. Any number of reasons that were in the respondents’ minds could have been given. In addition there was opportunity for further reasons in the open comments. There was almost complete ‘agreement’ from non-HSE users about the most important reason for WPE (Table 6.3).

Interview data offered further, more detailed accounts of how underlying principles concerning the focus on the natural WPE influenced choice of herb preparation.

No. 2 explained explicitly how they made a choice to practice in a way that does not use HSE and viewed using HSE as incorporating a different way of practicing that they are not ‘trained’ in, that is at odds with their underlying holistic principles:

‘...it’s not why I came into herbal medicine.... I came from orthodox medicine, so obviously that’s all about focusing in on tiny little actions... I was attracted to herbal medicine obviously because of its being holistic in nature.....going down the standardised extract route always felt like a backwards step for me...Having a view, being aware of alternatives but choosing not to practice in

that way...Maybe in the same way as I wouldn't use aromatherapy internally, because I don't understand it enough. I'm totally comfortable and safe in using herbs in 1:3s (tinctures)....I do what I feel comfortable treating, I don't experiment really'

No. 8 strongly defined herbal practice as based on use of WPE:

'...that's what we serve to do – we stand for whole plant medicine'.

Other interviewees made comments about focusing on a non-scientific approach to practice.

No. 3 described their practice:

'I operate in a low dose range; I use herbs for their quality rather than their quantity so....I have pretty naturalised approach, a non-science-y approach, a non-measure-y approach...'

And No. 1 also indicated a traditional non-scientific 'vitalistic' approach:

'energy trumps matter in my experience...It's quite old-fashioned of me; I'd rather rely on the things that we've always relied on which are the plants themselves'.

No. 3 viewed the issue of WHM practice as split into 'the art and the science' and rates the 'art' more highly:

'the art is higher than the science.....the art can be defined and elucidated more; science just tends to be a bit thick about stuff in my opinion, it only goes so far'.

Central to traditional WHM practice is the idea of complexity. This issue was reflected in interview data, however there is no specific mention of complexity in survey data. This may however be implied in references to the 'natural approach'.

No. 8 discussed how this complexity is a reason for not concentrating constituents in HSE as, by the definition of complexity, there is insufficient evidence for manipulation of the WPE:

'Frankly....we're never going to know (what matters) – there are maybe 500 constituents in any one plant...But understanding humans and life - it's all about complexity....we don't even know if curcumin should be absorbed or not...is it that some (constituents) go into the bloodstream and some work on the gut wall instead....it's so complicated...the more I do this thing the more I think how little we know...this question about what is the mechanism of

action...who knows...So I want complexity – that’s what we know is effective for us. ...I’m puzzled as to whether standardised extracts in terms of using certain standardised markers is the sensible way to go, or not...’

Similarly No. 13 echoed this lack of evidence for WPE manipulation:

‘It is my belief that it is virtually impossible to know without doubt which constituent has a given effect, and furthermore, that that effect may well not occur if the balance of constituents is altered’.

No. 2 discussed deciding to ‘trust’ nature rather than altering the constituent balance and risking losing the natural balance:

‘And without ever researching it or looking into it my assumption was if you standardise on one constituent just how do you decide which constituent to standardise on, because I know we’ve made errors with things like hypericin...and then does the standardising of one constituent mean that you have to forfeit levels of other constituents and therefore you lose the synergy....so it was that if we’re trusting two living things to work in harmony i.e. the body and the plant erm, the trust should be the plant has got the balance right with the body and it’s like a communication between these two things and if we start interfering.....you might end up with side effects, and an absence of harmony and synergy’.

No. 13, similarly discussed ‘trusting’ nature to offer safe medicine, with reduced risk of side-effects:

‘I think nature does actually know what it’s doing erm and has been doing it for a very long time without our manipulation, why would we not trust it; I think that’s kind of where I’m coming from with that’

An alternative view of complexity however was offered by No. 11 who reported:

‘I think in times to come modern science will end up understanding as well’

The natural presentation of herbs is therefore a major influence in use of WPE in WHM and this was discussed. No. 8 talked about ‘evidence’ for complexity:

‘I believe in practicing complex medicine for complex people. I’m also very aware of evidence for my prejudice because I know we’re complex and we know that we thrive on complexity and we know that there’s this thing called synergy, although we don’t know a lot about that either’.

And No. 8 also discussed organoleptics (sensory testing) as a solution for determining quality of preparations. This relies on the complexity of the plant and which is obviously is not applicable to HSE as they do not offer information via taste or smell:

'the taste buds I think ARE satisfactory to some extent but what are you judging it against; you're judging maybe the hit that you get and the complexity – what I would go for, my bottom line I suppose is complexity, but that is incredibly subjective, not the complexity itself, that's a real thing and super-important in everything and my taste buds are 4.5 billion years – so I know that that's a very useful helpful way of showing complexity....when you taste something that is telling you if it has something in it or nothing in it and some of the tinctures I use I think 'cor' there's not much in this.....I do think organoleptics are really important – what else have we got to go on?'

No. 6 also discussed the importance of taste in WHM:

'I do very much subscribe to the taste hypothesis – that the taste of the medicine is rather important and if you lose the taste you could be losing quite a lot of the impact of the medicine. I think the taste is important so I would be hesitant to lose the taste by using SE'.

Although an issue with HSE is the reduction in complexity and synergy, some HSE users believe that HSE retain an important element of synergy. No. 7 stated:

'it's (HSE) not just a single compound because I think there is the synergy that we need and the synergy is there not just for effectiveness, the synergy is there also for safety as well, because a lot of the synergistic compounds seem to have roles to reduce toxicity so again if you use a single compound, toxic effects are much more common'.

No. 6 also believed the synergy is retained:

'if one is making something standardised it doesn't mean one is losing elements of the synergy – they might not have everything in it but one has something important which is standardised and then hopefully the rest of other things around it which are maybe complementary and balancing, or that support or increase absorption or affect the pharmacodynamics or kinetics in some way'

Related to the issue of using WPE based on the natural approach is the specific issues of how HSE are seen as 'products' that are further along a spectrum to becoming like pharmaceuticals,

without the level of complexity in the WPE. This is reflected in survey data with 5 responses to Question 3 (Appendix 12, p. 246) stating this issue and 6 comments in Question 28 (Appendix, 12, p.250), open comments from non-HSE users (see Table 6.5 and Appendix 14, Q 28). There were no similar comments from HSE users in survey data, however in interviews both non-HSE users and HSE users made comments.

No. 3 described the use of HSE as using 'products':

'I think that word products ...I don't use productsI think it's just a non-pharmacological version of selling a thing that becomes big pharma if you take it further.'

No. 9 stated that:

'I'm just not into (HSEs)...Er – it's the tampering....I see standardised extracts as pseudopharmaceuticals'

No. 1:

'(HSEs are like) ...pharmaceuticals by another name really; manufactured'

No. 13:

'I think that.... (HSEs).... are a little bit further along the road between herbal medicine and conventional medicationso I'm a little bit wary I guess...This, in my opinion, then turns the plant, and the way it has been used safely for generations, into a pseudo drug, potentially with adverse effects.'

The interview arena may have allowed for a fuller discussion of this issue from HSE users, and suggests that it is an issue across the community. No. 11, who reported using HSE, expressed concern:

'I wonder whether the more standardised it becomes, the more we're kind of erring towards maybe becoming pharmaceuticalised'.

No. 7, who reported that they regularly use HSE said:

'...but I do admit and agree that that's a non-traditional non-herbal medicine use...that enters a grey area between herbal medicine and pharmaceutical drugs and I admit that totally'

Related to the nature of HSE being considered 'products' is the issue of commercial influence underlying decision not to use. Lack of trust in the supplement companies may lead to avoidance of those products and again both non-HSE users and HSE users expressed concern.

No. 1 felt that these HSE products were more about profit than therapy:

'a lot of this is commercial and marketing.... Nutritional supplement company seminars....ultimately they're there to flog a product..95 % curcumin seems to be the code for a money spinner'

No. 8: *'if one wants to go back and unpick all of this – follow the money'*

No. 2 stopped using *C. longa* HSE as a result:

'I did use it for a while but I stopped when I heard about the ethics of the company. That was my main reason for stopping'.

No. 12, an HSE user was also concerned:

'supplement companies...who've seen the band wagon and jumped on it and found a way to give the plants.... to a public who these days are more used to taking capsules'.

As was HSE user, No. 11 also questioned relying on non-independent HSE research:

'It's a cash cow really isn't it, curcumin....why are we relying on this modern research provided by pharmaceutical companies who have a vested interest'.

However, No. 7 reported a belief that HSE are necessary, despite the risk of products being considered more like pharmaceuticals:

'some people will accuse us of moving away from herbal medicine, moving into a more sort of pharmaceutical medicine'.

This central focus on the natural WPE was therefore particularly strong, not only amongst non-HSE users but also represented in HSE users in the survey and also in interviews.

As indicated above, reasons other than those concerning the central focus on the natural WPE above, were limited. They concerned the large fixed dose, side effects, clinical evidence from practice, recommendation from other herbalists, issues of quality and consistency, expense, sustainability, lack of need, intuition and herbal texts, below.

Both HSE users and non-users discussed the issue of HSE being a large and fixed dose. The issue of HSE doses being fixed was reported as a problem by 3 non-HSE users (6% of 54) in Question 28 'other comments', which indicated that HSE does not allow for *'the individuality of our treatment'* and *'The patients aren't standardised'*. In interviews this issue was discussed by both non-HSE users and also HSE users.

Non-HSE users in interviews reported HSE doses not being suitable or adaptable for using low doses if required for a patient. No. 3 reported that they only use low doses of herbs in practice:

'Personally as a practitioner I operate in a low dose range'

Other herbalists discussed the inflexibility of the HSE dose, which by its nature is not adaptable in the same way as WPE which are tailored to the individual. No. 1:

'Different people respond differently to different dose levels.....it goes against the individuality of our treatment that you can manipulate the dose to suit the patient; I feel very strongly. ...For example, Mills and Bone say 'this level' and sometimes I found this is too much; sometimes a person needs smaller doses.....Some patients, often those who respond well to homeopathy and are sensitive to pharmaceutical drugs; with herbs, need to go in low with them. Standardised extracts are not useful for those folks.... We're trying to fit everybody into a pharmaceutical model – this is the dose, this is the herbal extract, it will fit everybody and be wonderful for everybody'

A survey respondent who reported use of HSE suggested that they are not suitable for all:

'On sensitive individuals, it is best to only use whole plant extract with lower potency but wider spectrum of therapeutics and freshness of energetic qualities'.

Another HSE user, No. 11, reported being conflicted about the use of HSE, discussing the issue of large doses 'forcing' a response in the body, as well as the lack of individuality in the approach, which is central to WHM:

'if you have to use such huge doses.....to get something flowing then I'd question what's the logic behind using it, erm, there's obviously something else standing in the way that you have to address first. And with for example curcumin – by giving huge amounts maybe we will actually force the body to take some on board but is it the right way of doing it because if there is a natural barrier there perhaps we should actually listen to the body and recognise that perhaps the body knows better, that we have got those barriers there and perhaps they're there for a reason...this is where it gets a bit awkward, I suppose, to be perfectly honest.....we have to be aware that people are individuals...the important thing of herbal medicine and natural medicine as a whole really is to treat people obviously as individuals, erm so it somewhat

detracts from our ability to use our own common sense to help people. So yeah, it's a bit of a catch 22'

Unwanted side-effects with HSE were a minor concern for both those who use HSE and those who do not in interviews and survey. 10 % (n = 7 of 72) of respondents reported noticing side effects and 22 % (n = 16 of 72 respondents) reported either noticing side effects from HSE products or being 'not sure' in Questions 18 and 19. None reported submitting a yellow card detailing the side effects. Apart from 2 herbalists who were 'not sure', all who reported possible side effects were non-HSE users. It is assumed that they may have either used HSE in the past or observed these reactions in other circumstances and have made decisions not to use HSE. 4 non-HSE users in the survey questioned safety for recently developed HSE products pointing out the lack of 'long term safety data' and 'more research' needed. Stated side effects were from *C. longa* HSE (4 statements related to clotting and digestive issues), *G. biloba* HSE (headache), *S. marianum* HSE and *Cordyceps Spp.*. Side effects reported were minor and with no reported submission of a yellow card were likely to have been considered not significant. However in interview data, HSE users also expressed concern about side effects:

No. 12 who reported use of HSE was cautious since reading about potential side effects:

'I already know that turmeric could in some cases cause anaemia and restrict iron absorption; and then there was something on the Facebook group or on the news and somebody reporting becoming anaemic having used a standardised extract of turmeric, and that made me think yes we do have to be careful with this'.

No. 7, although they reported frequent use of a range of HSE, cautioned of potential side effects of green tea as an HSE. The risks associated with epigallocatechin gallate (EGCG) have been supported in a recent review (Oketch-Rabah et al., 2020).:

'...green tea is very safe but....concentrated EGCG supplements...they're more (like a) pharmaceutical drug....there have been incidences of liver toxicity with them....you're putting huge amounts of these things into your body, the polyphenols, some of the metabolites are quite toxic...you start to have the same side effects and danger profiles that you do with conventional pharmaceutical drugs...I think as soon as you start getting away from non-traditional extracts... there's a huge risk of toxicity issues'.

No. 13, who reported no longer using HSE, discussed a retinal haemorrhage which occurred at the same time as taking *G. biloba* HSE, saying:

'...(I) stopped taking it, the haemorrhage resolved and...haven't had another one since and that's been 7 or 8 years'

and also discussed evidence for the natural form of the herb as being safer for the body:

'...if it's available in a natural form, why would we not use it in its natural form....when it (Filipendula ulmaria) was honed down to aspirin...people got gastric bleeds but when it's given in its whole form, not only does it not produce gastric bleeds, it protects against them...'

Evidence of clinical evidence from practice was a minor reported influence on the choice to not use HSE. Limited evidence was from a survey respondent who stated that when they are 'tempted' to use HSE they are reminded by others 'how effective our plant medicines are'. In addition, similar to HSE users above, there were reports of comparison between WPE and HSE where the WPE was found to be preferable to the HSE, although only a small minority of non-HSE users reported this compared to HSE users. Comparisons were reported for *C. longa*. The WPE was found preferable in 3 cases in the survey (6 % of 54 non-SE users) for joint pain and with fewer side effects (see Table 6.10, p. 141). Interview data also indicated evidence of comparison.

No. 10 reported having used HSE in the past and said:

'I haven't seen any reduction (in outcomes since replacing HSE with WPE)'

No. 9 explained accumulating evidence for WPE *C. longa* in the many patients with MS that they have treated:

'...I've just seen MS over and over again...little by little I noticed trends that they (patients) were starting to notice the difference.... So it was more hitting the ground running, it's not very scientific, but overall I can't think of anyone who has preferred the standardised extract. Whenever I've tried them they've always gone back to using the capsules....They seem to say that they're so much better for them than when they were taking the standardised extracts..... ultimately just try it and see...my feeling that I'm seeing on the ground is that it works so much better if it's the whole extract'.

Other evidence came from patient preference. No. 1 reported evidence from a patient who preferred *C. longa* WPE to the HSE:

'I have a patient who takes the whole spice in capsules rather than curcumin. He finds them definitely the best.....he's tried curcuminoids'.

Now considering the influence of other herbalists on WPE use, although reported influence of other herbalists is reported relatively less frequently than for HSE use, there was some overt evidence of influence. No. 2 said that they're '*more likely to listen to...other herbalists...or...materia medica (than follow research)*'. In addition although No. 12 was influenced to use HSE by a respected herbalist, they were also influenced more recently following a seminar by an herbalist who does not use HSE and are now thinking more about the topic and using HSE less:

'...my thinking has changed....I didn't really used to think about, too much about whether something was standardised or not and if there were times that I thought I needed something in higher dose I would use a standardised extract and not worry too much about it...I was already mulling over these ideas about what standardised extracts were and how I felt about them...(and) I've rethought some of it after going to (NAMED HERBALIST)' seminar on progressive neurological disorders, Parkinsons and MS, last year...she does lots of work with people with things like MS and Parkinsons and all she's using is what she called kitchen table pharmacy; she would just use powdered turmeric, with some black pepper and make the capsules herself and was getting great responses and I thought, hmmm that's really interesting....it alerted me that that was something I really needed to think about.....So I think my thinking is still a bit mixed on it but I'm much more in favour of that kitchen cupboard type pharmacy now'.

Another issue that was reported in interviews was quality and consistency. Interviewees mentioned quality of both WPE and HSE, however this wasn't brought up in the survey.

No. 11 stated: '*standardisation is a process which can go either way, you can have a bad batch*'

No. 8 discussed research which questioned the quality of OTC HSEs:

'If nobody's independently assessed these things; very worrying....it's only when you learn how adulterated they are or absent they are that you really worry about what you're giving. So apparently the THRs came out fine from the research - they were what they said they were – the registered products, which is good'.

The expense of HSE was stated as a factor in not using HSE, by 3 Interviewees and 3 survey respondents. No. 1 and 4 both stated that they're 'expensive' and No. 12 worried about the financial burden for already stressed patients:

'I don't think that's achievable for everybody and also it puts people who are already quite ill under a lot of pressure '

No. 1 was concerned about recommending expensive supplements that they are not confident in using:

'I don't have the knowledge.... last thing I'd wish is to be pedalling something very expensive to people in vulnerable situations and maybe not what they need'

Two interviewees brought up the issue of sustainability, but this issue was not mentioned in the survey.

No. 11 stated:

'I believe the amount of turmeric you need to produce 1g of 95 % curcuminoid is ridiculous and also looking at it from a holistic point of view if we had to take up ...if we had a miracle cure for something but we had to destroy half the rain forest to get itshould we do that really'.

and No. 8 stated:

'there's another whole subject here, which is about what's sustainable - if you're using 95 % curcumin, what are you doing with the rest of it?'

Other herbalists reported not having had the need in practice for HSE or haven't considered it: No. 13: *'standardised extracts are just one of those things that I haven't had the need to go down that road particularly often'*

No. 1: *'I haven't found them useful yet'*

No. 2 reported not having looked into the option of using HSE:

'I work with the people I want to work with, in the way I work, so it's kind of that's the avenue I'm going down so I haven't looked into it any further than that...I don't use standardised extracts and it's not something I've really given lots of thought....think it's something I rejected outright without erm going this is something I need to give consideration'

No. 4 similarly reported that they haven't actively looked into the research:

'I don't do a lot of reading up relating to research that may or may not be occurring so maybe I'm head in the sand a little bit in terms of change. I like to read what come through from the institute but I don't go hunting for research to widen my knowledge.... I'm pretty ignorant relating to standardised extracts..... because I haven't gone looking for them'.

In addition, interview data also suggested an element of 'intuition' or non-logical processes in herbalists' decision making. A search on WHMQ provided 98 posts which referred to 'intuition' since 2012 (0.43 % of posts), however this was not recorded in the survey responses.

No. 2 stated, discussing belief in loss of synergy with HSE:

'(I) rejected it without any research and just gone on a feeling' I'd use all of those together – getting a better hit than just using the SE/curcumin. Never read any research on it, just that feels right'.

No. 1 said similarly:

'All this is instinctive on my part; nothing solid and scientific; perhaps there ought to be'.

No. 3: *'I have pretty naturalised approach, a non-sciencey approach, a non-measurey approach'*

No. 8 admits their prejudice against HSE supplements:

'I'm quite suspicious about supplements in general except judiciously used, maybe short term – but that's my prejudice again.... My prejudice is against them'.

6.3.2 Reduced use of HSE – evidence for historical use that has not continued

There is limited evidence from the data that HSE was used historically by some herbalists who have since stopped use.

Considering direct supportive evidence of herbalists having used HSEs in the past but having stopped, there is limited evidence from the survey. 11 % of non-HSE users (n = 6 out of 54 responses) reported using HSE in the past, specifically stated as *C. longa* HSE (n = 4), *S. marianum* HSE (n = 2) and *G. biloba* (n = 1).

There is also evidence that herbalists may have forgotten about past use. No. 2 remembered that they used to use it at the end of the interview: *'I'd forgotten about using that'.*

Data from the survey and interviews offers suggestions for this lack of persistence with HSE use. It may be due to lack of clinical evidence in practice following historical influences from other herbalists. It may be related to moving back to a more traditional approach, with increased focus on WPE, following a relatively brief focus on the HSE.

No. 10 reported being influenced in the use of HSE *C. longa* after advice from a respected herbalist but has since stopped using it after finding no additional benefit. In addition a survey comment stated that the herbalist saw '*...side effects...when.... (they) ...used to use them*'.

Considering the possibility of reduced HSE use due to a renewed focus on the WPE, this was suggested by No. 13:

'I would say I was (open-minded) and I'm less so now. The longer I've practiced, the more I've moved away from anything that smacks of conventional medicine – don't get me wrong, I'm not knocking medicine, when we need it we need it...'

6.3.3 Attitudes towards HSE: Widespread open-mindedness to HSE, limited reported strong feelings against HSE, reduced controversy and clarity of choice.

Following on from the presentation of lack of positivity towards HSE and strong, possibly renewed focus on the WPE, it was found this was not reflected in reported strong feelings against HSE. Only limited evidence of controversy was noted. Widespread open-mindedness towards HSE was found, although with a central 'split' in the herbal community. However there were no signs of lack of clarity in choice of preparation. All but one identified 'open-minded' herbalists reported being trained in research analysis.

General open-mindedness in the herbal community was measured through responses to Questions 20 and 21 about whether they could imagine the most likely HSE that they would use in practice. Those who either reported use of HSE or reported that they could imagine a most likely used HSE were considered to be open-minded. Of the 52 non-HSE users who responded to Questions 20 and 21 about, 35 % (n = 18) identified an HSE (2 non-HSE users did not reply to Questions 20 and 21). Therefore over half, 55 % (n = 42 of 76) of responding herbalists reported either using HSEs (n = 24) or could imagine using HSEs (n = 18) in practice and 45 % of those responding (n = 34 of 52 respondents) were non-HSE users who could not imagine a most likely HSE. These questions asking about 'most likely identified situation for using a named HSE' were used as a measure of 'open-ness' to using HSE and these figures represent a 'split' in the herbalist community between those who use or would consider use of HSE and those who would not consider use. In addition, 67 % (n = 12) of CPP members

reported either using HSEs in Question 2 (Appendix 12, p. 246) or reporting that they could imagine using HSEs in Question 20 (Appendix 12, p. 249). This is a far higher figure than found for the other PAs as outlined in Table 6.3.

However, it is recognised that this method of assessing open-mindedness is a crude measure. Specifically, those non-HSE users who answered 'yes', that they could identify a most likely used HSE, were assumed to be open to use of HSEs even though they did not use them already. However, these figures may also be an underestimation of open-ness to HSE use; the question was slightly ambiguous and there is the possibility that 'no' responses may also mean that the herbalist could not think of a most likely HSE example at that time. This was seen in a small minority of HSE users reporting that 'no' they could not think of a most likely situation where they would use a specific HSE. It may be suggested that non-users are more likely to mean that they would not consider use by answering 'no' here but this is just an assumption. The results are therefore treated cautiously, with the understanding that there may be more non-HSE users who are 'open-minded' about HSE than the data suggests. Nevertheless, the data does appear to suggest a significant split in the herbal community between those using or considering HSE use and those not currently open to HSE use.

Further evidence about this proposed 'open-mindedness' split in the herbalist community came from analysing the open comments (Q. 28) in the survey which were made by non-HSE users. A noticeable split in comments was found (see Table 6.5, p. 99) which suggested different attitudes towards HSE. Comments from non-HSE users were identified that were considered to relate to either open-mindedness or not, towards HSE. Of 11 commenting non-HSE users who stated that they would consider HSE use in Question 20 (Appendix 12, p. 249), 7 reported in open comments, Question 28, that they would like more information about this issue, suggesting open-mindedness. However, of 15 commenting non-HSE users, who did not state that they would consider using HSE in Question 20, 6 reported that they viewed HSE products as moving towards a more 'pharmaceutical' approach. Again, this suggests that non-HSE users are split into those who are 'open-minded', open to HSE use and looking for further information about choice of preparation, and those who are not open to HSE use and are concerned about the nature of HSE products being more like pharmaceuticals.

There was even less evidence of 'anti-HSE' views in interviews. Non-HSE users suggested only open-mindedness, even if they did not currently have a use for HSE; comments included expressions of open-mindedness, respecting other herbalists' use of HSE, although also expressing some reservation about use:

No. 8 reported being open-minded: *'I'm always having an open mind; I want to learn; if I get convinced....'*

No. 9 discussed still being open-minded after comparing *C. longa* HSE to WPE in practice and being surprised by preferring WPE:

'I was in two minds initially and went into it quite open-minded because of that.....gradually you start to see repeating patterns, that I wasn't expecting to be honest.....I might consider doing that (using S. marianum HSE) but I haven't quite decided.....If somebody comes to me and they're taking standardised extracts I never say to them 'don't' – I often do say to them what my thoughts are – you know, this school of thought – I'm quite open minded so if somebody was there saying that they were getting great results, I'm a big believer in if you've got a winning team don't change it'

No. 1 reported on the possibility of changing their mind:

'I've changed my attitude to things over the years e.g. probiotics; initially thought could do it with diet.....There may be times when... (HSEs)...are appropriate'

Other non-HSE users explained more about when they might use HSE. No. 5 reported that they would put patients first:

'ifits going to help somebody then that's fine'

Similarly, No. 4 would be happy providing HSEs if a patient wanted it:

'I think if a patient came through the door and wanted treatment and was saying erm I'm using standardised turmeric and I want to carry on using that and I want to get all the herbs from one source and I'd like you to provide it, if I thought they were someone who was going to stay then I wouldn't have a problem in going out and getting standardised turmeric for them'

No. 12 also considered a 'good reason' for HSE use includes supporting patients who wish to take them:

'I always support my patients in their choices and the bottom line for me is quality of life.....I support people in whatever they feel they need to do....I don't add to their burden by saying you shouldn't do that'

No. 13 reported that they would consider HSE if appropriate:

'I think in some instances it's yes, if you're using it for a specific purpose then yes I would probably have another look at it'.

Although No. 4 would want sufficient evidence:

'...before I would use standardised extracts I would want to have some kind of confidence that it was providing added value rather than just simply 'oh yes that's quite good as well''

No. 8 would also need convincing evidence:

'Well there is research on turmeric and curcumin and it would have to be - I'm not going to fly in the face of what's there, if there's really overwhelming evidence that curcumin - for a particular condition - was clearly head and shoulders above anything else, well I'd be mad not to ...in serious illness or requirement of high dose'

Others were more fixed in their position but respected others' choices. No. 2 accepted that others find HSE useful in their practice:

'Not my expression of herbal medicine but I would absolutely go 'that's working in those situations', great'

Similarly with No. 3:

'I recognise their value but I hand over because I feel my expertise ends so I focus on other bits; I focus on energy medicine'.

However, No. 4 was more cautious:

'I think I'm not opposed to them...I think I'm dubious....I'm against them to a degree but I'm not saying that I'm overwhelmingly, adversely adverse towards them it's just that I remain pretty unconvinced'.

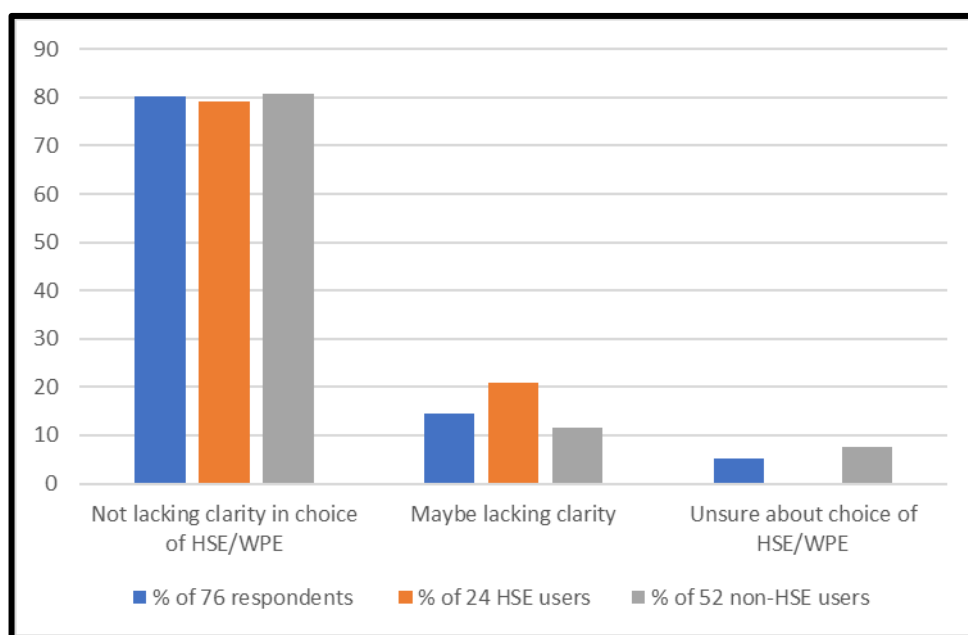
Expressions of only open-mindedness in interviews despite the identified split in the survey suggests an element of controversy remains. The only overt evidence for this was from interviewee No. 7 stating that herbalists did not want to 'admit' to non-traditional practice. Other comparisons between interview and survey that suggested remaining controversy was strong reported clarity in the survey yet a lack of clarity in interviews. This difference in reporting between survey and interview may suggest 'caution', due to controversy, in interview responses compared to the anonymous survey. Other evidence that may suggest remaining controversy is that it was difficult to recruit interviewees who used HSEs, yet a large

minority of the herbal population reported HSE use, therefore it may be suggested that the anonymous nature of the survey encouraged HSE users to take part. It might be proposed that a discussion of HSE use would be more challenging to discuss as a recently adopted aspect of practice. However there is no evidence of lack of confidence in the topic from HSE users' survey responses about clarity. HSE user interviewees discussed HSE use in 'serious' conditions and survey data HSE users focused on 'everyday' conditions. This may suggest interviewees 'justifying' HSE use due to controversy. However this is rather suggested to be due to interviewees being more experienced practitioners who focused more on 'serious' conditions such as cancer. It is therefore suggested that an element of controversy remains, with the anonymous survey having allowed positions that may have been modified in interview.

Now moving on to how clear herbalists claimed to be about their choice of preparation, reported clarity was very high. This may relate to the strong focus on WPE, the lack of reported strong feelings towards HSE and reduced controversy. This may make decisions easier as thinking is not clouded about conflict between HSE and WPE.

Survey results showed that 80 % of 76 responding herbalists reported in the survey that they did not lack clarity about choice of product (only 5 % reporting 'yes' that they were unsure; 15 % said 'maybe'). HSE users reported being even more sure about their choice with no HSE users reporting 'yes' to being unsure (although 21 % of 24 respondents reported 'maybe') (Figure 6.3, below). A significant minority (n = 6; 25 %) of HSE users in the survey made comments indicating clinical use of both preparations together (from data in Question 8a, Question 12a and Question 16, see Appendix 12, pp. 247-61), therefore avoiding choice of either preparation alone, which may assist with clarity of choice and none of these herbalists stated that they lacked clarity.

Figure 6.3: Chart to show reported clarity of choice of HSE or WPE (Question 13, Appendix 12, p.248)



In addition, supporting these overt survey answers about clarity, the strong focus on WPE also supported claims of clarity and there were no additional comments that indicated a lack of clarity about choice of product. Comments were limited to one herbalist who stated *'It would be useful if the professional bodies would advise or issue guidelines'*. This lack of clarity was the starting point for the author in carrying out research on this topic.

However, in contrast to the survey data, in interview data a lack of clarity was a common theme amongst both HSE users and non-users (as mentioned above in the consideration of controversy above), who used words such as *'awkward'*, *'confusing'*, *'not ...convinced'*, *'very complicated'*, *'make (it) up as you go along'*, *'don't know'* and also HSE users: *'not...sure'*, *'my thinking is...mixed'*.

Considering non-HSE users:

No. 1 reported an element of confusion in which preparation to use and sticks to what they are comfortable with:

'I do not truly know if standardised extracts are more efficacious in contrast to whole plant medicines....I give patients information but leave it up to them to decide – I don't have the knowledge....I will recommend things that I'm confident in i.e. the herbs I work with on a daily basis and over the years'

No. 8 discussed lack of clarity around dose of *C. longa* to get 'enough':

'There's another whole aspect of this, which is, although I tend to say 2 teaspoons of turmeric – but I tend to think, and I do tend to say this to people, they say well if I use fresh turmeric in my smoothie and I'm using that sort of amount, is that enough and I think probably not and so I often say do both or do a teaspoon of turmeric powder, as you're getting much morebut the point is that you've also got somebody who's got the lovely juicy turmeric root – maybe that's doing something, maybe that's medicinal in other ways. So yes I think it's very complicated and we want to mobilise all kinds of healing approaches'.

No. 9, a non-HSE user, discussed the lack of clarity in possible HSE use and having been conflicted in the past:

'You make all this stuff up as you go along, don't you, that's the reality... when I first started out in practice I was still in two minds; I was still indoctrinated with the idea that you don't want to alter things, you want whole herb extracts, you don't want to isolate your constituents...so I had all of that in my mind but also I'd been to a lot of (NAMED HERBALIST)'s talks and the like and all the strengthened stuff and certainly (NAMED HERBALIST) and all cancers and you want to have all the strengthened....so I was in two minds initially'

It is striking that HSE users also expressed lack of clarity:

No. 6 who reported relying on research stated:

'I think it's an awkward one 'cos we have to strike a balance and use things to the best of our knowledge.'

No. 12 discussed being unclear and addressed this by mixing HSE and WPE preparations, as was also found in the survey:

'So I think my thinking is still a bit mixed on it...I'm not sure how I feel about it because for me it does still sometimes have a place, but it wouldn't be my first port of call with people.....(if) in doubt, I purposefully mix whole plant extracts with standardised extracts to have different phytochemical therapeutics and enhance the potency of the prescription'.

No. 11 reported using only *S. marianum* and *G. biloba* HSE, but *C. longa* WPE and admits an element of confusion in their position:

'So that's the dilemma I've got – I do believe in standardised extracts, to follow the research and replicate the same results and ironically perhaps I'm a bit two faced as I'm aware that a lot of the research has been done on certain doses and you don't need those doses to get the beneficial effect' and 'it's totally unscientific to say why I would use turmeric non standardised' and 'I'm not sure if there's any detriment in using a plant without it being standardised, but I do find myself, I always have, to be perfectly honest, I'm not entirely sure why, finding myself actually using the standardised extracts'.

No. 6 discussed the difficulty in deciding what information to rely on when making a decision about choice of product:

'it's all very complicated. So if you're trying to make a decision about what to do how do you make your decision - do you make it based on talking to your friends, case studies, going to seminars, maybe a bit of marketing by a provider of some kind of medicine...lots of different variables'

No. 11 strongly defended HSE use and then questions that position:

'It amazes me the amount of people that nowadays still use for example milk thistle as a 25 % ethanol content which research has shown does not contain appreciable levels of silycristin, silymarin and so on; that for me is on the one hand a bit worrying and on the other hand maybe we're missing out on something here because obviously our forefathers just used to make a tea and have some beneficial effects and so perhaps they don't need to be standardised'.

These expressions of lack of clarity, although they may suggest some element of controversy in the topic of HSE, are also informative. Decisions may be made clearly but there may be more complex thoughts underlying them that maybe do not impact on that decision-making.

6.3.4 Reasons for clear choice of HSE largely based on research, evidence of 'strong' characteristics from practice and other herbalists.

Results so far have suggested widespread, but individually limited HSE use, that may reflect somewhat passive open-mindedness towards HSE, and over-shadowed by a strong commitment to WPE. The discussion now moves on to consider reasons and influences behind the reported clearly made decisions that have led to use of the mildly controversial HSE. Although a wider range of influential factors were offered by HSE users compared to WPE users, it is striking that virtually all reported using HSE based on research evidence and clinical findings of 'strong' characteristics from their own practice. Other frequently reported factors

were recommendations from other herbalists or herbalist seminars, large dose and use in everyday conditions. In general, data suggests a relatively clear picture of how herbalists have come to use HSE. This may have started with recommendation from other herbalists and/or research and use has been continued following supportive evidence from practice based on 'strength' of HSE in 'everyday' conditions, rather than serious conditions. An overview of major reasons are reported below, followed by more in depth considerations of each, and finally more minor reasons.

Of reasons and influences given for use of HSE from Questions 7 and 8 (see Table 6.6 below), all 24 HSE users gave answers to these questions. The major reason was stated as 'more effective' by 63 % (n = 15) of HSE users. Having a 'specific activity' (54 %; n = 13), being 'stronger' (42 %; n = 10) and being 'easier to take' (42 %; n = 10) were also common reasons. Only 8 % (n = 2) of HSE users stated they are 'easier to take' as the *only* reason, the rest all included answers related to the first 3 options about strength and action.

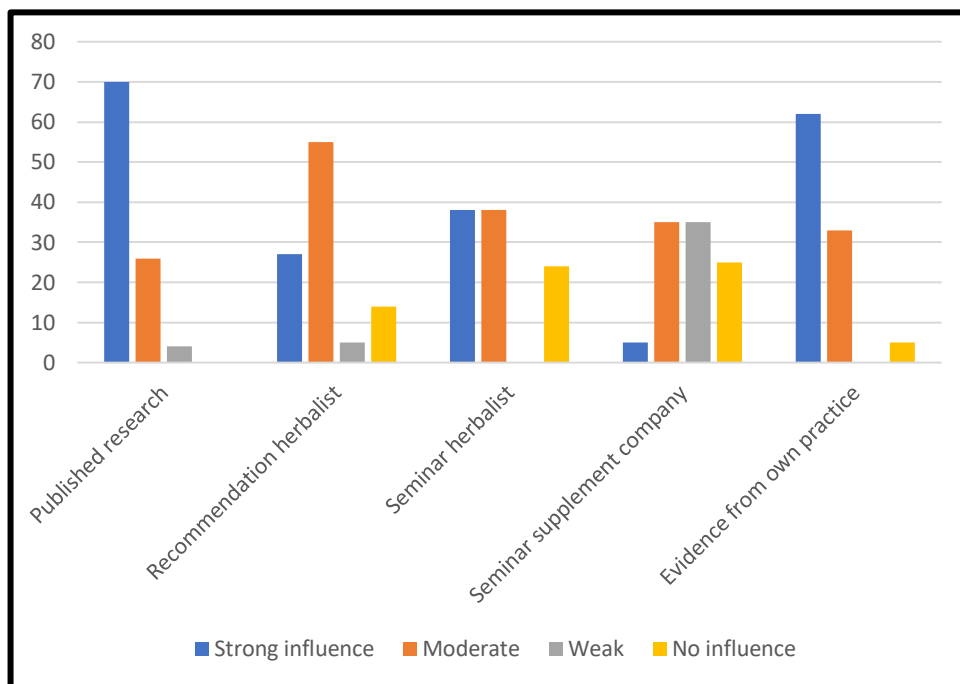
Table 6.6: Reported reasons for using HSEs (Question 7, Appendix 12, p. 246).

Reasons for using HSE	Number of respondents / % of those 24 who use HSE	Number who state only this one reason for HSE use / % of those stating reason
More effective	15 / 63 %	2 / 13 %
Stronger	10 / 42 %	4 / 40 %
Use for specific action	13 / 54 %	5 / 39 %
Easier to take	10 / 42 %	2 / 20 %
Other (detailed above)	4 / 17 %	0

Considering reported influences on HSE use (see Figure 6.4 below), the strongest influence (from Question 7, Appendix 12, p. 246) was stated as 'research'. 70 % (n = 16 of 23 respondents) stated it was a 'strong' influence on HSE use and 96 % (n = 22 of 23) stated 'strong' or 'moderate' influence. No HSE users stated that published research has no influence. The second strongest influence was stated as 'evidence from own practice' with 62 % (n = 13 of 21 respondents), reporting that it had a strong influence and 95 % (n = 20 of 21) stating strong or moderate influence. These major influences were reported as more influential than seminars by or recommendations from other herbalists, with 38 % (n = 8 of 21 responses) and 27 % (n = 6 of 22 responses) respectively stating a strong influence and 76 % (n = 16 out of 21 responses) and 82 % (n = 18 out of 22 responses) respectively for a strong or moderate influence. In addition, combining the figures for the influence of other herbalists, 50% (n = 11

of 22 responses) reported a strong influence for *either* recommendation from other herbalists or herbalist seminar and 82 % (n = 18 of 22 responses) reported a strong or moderate influence. The least reported influential factor was supplement company seminars with only 5 % (n = 1 of 20 responses) stating a strong influence and 40 % (n = 8 out of 20 responses) stating a strong or moderate influence and no evidence of positive influence in any other data. There was only one mention of the Lamberts brand in the study, Lamberts having offered widespread free seminars to health practitioners historically.

Figure 6.4 : Chart to show reported influences as % of responding HSE users (Question 8, Appendix 12, p.247).

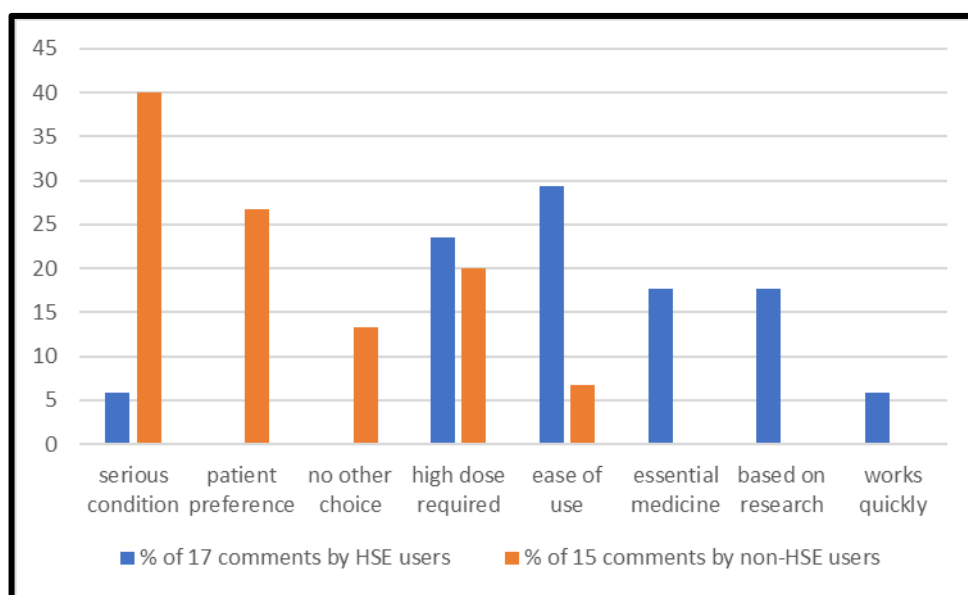


Further data concerning explanation for use of HSE came from reasons for most likely HSE use, Question 22 (Appendix 12, p. 250). This was answered by HSE users and non-users. Non-HSE users answered about theoretical use. The answers were open and comments were categorised as represented in Figure 6.5, below. This offers a comparison of reasons for use between HSE users and non-HSE users who nevertheless can think of a potential use. There was a distinct difference between reasons stated by HSE users and non-HSE users. HSE users were most likely to state that the HSE is related to everyday conditions (such as musculoskeletal pain), research evidence (reflecting research as the strongest influence above) and requirement for a high dose (reflecting evidence of ‘strength’ from clinical practice above). Non-HSE users reported they would be most likely to use HSE for a serious condition, patient preference, if there was no other choice or, like HSE users, if a high dose was required. (Figure 5).

Investigating these contrasting findings between HSE users and non-users, a brief review of the research was carried out. This showed that HSE users' reports of use in 'everyday' conditions is supported by the research more than non-HSE users' reports of use in 'serious' conditions as explained below, suggesting that HSE users were more aware of the HSE research. Reviewing research supporting HSE use in 'serious' conditions, such as cancer and autoimmune conditions, a review of human RCTs from 2018-20 for '*C. longa*/curcumin/curcuminoids' yielded 110 studies on PubMed for HSE *C. longa*, of which 99 (90 %) were studies on general inflammation / oxidation mainly in metabolic conditions, arthritis, neurological issues. Only 10 % related to conditions which may be considered a greater threat to life and more 'serious' – 7 (6 %) related to cancer, 2 (2 %) related to ALS and 2 (2 %) related to multiple sclerosis. This is also reflected in identified recent systematic reviews and meta-analyses largely focusing on these conditions (Appendix 3). For *G. biloba*, from 2018-20 there were 10 human RCTs identified on PubMed, none related to 'serious' conditions (they related to hearing (n=33), glaucoma (n = 1), cognitive issues (n = 3), diabetes mellitus (n = 2) and hypertension (n = 1). For *S. marianum* HSE, 12 RCTs were identified from 2018-20 (metabolic conditions (n = 6) and 1 each of menopause, vitiligo, acne, dermatitis, iron chelation, galactagogue).

Considering interview data, non-HSE users reflected these findings from the survey, with Nos. 1, 2, 9 and 13 reporting that they would consider HSE only in 'serious situations'. However, despite survey data suggesting common use of HSE for 'everyday' conditions by HSE users in Question 22 (Appendix 12, p. 250), rather than 'serious' conditions, interview comments from HSE users almost exclusively discussed use in serious conditions. HSE users No. 5 and 7 both reported using HSE in cancer support and No. 6 reported only using HSE *G. biloba* to support a patient with schizophrenia.

Figure 6.5: Chart to show differences given in reasons for use of most likely HSE between HSE users and non-users (Question 22, Appendix 12, p.250)



6.3.4.1 Evidence concerning use of research, the strongest reported influence on HSE use

Now considering reasons and influences for HSE use in more depth, further evidence concerning research, stated as the strongest influence in Question 7 (Appendix 12, p.246), is detailed below. Evidence suggested widespread, but limited, use of research and this was found across the responding survey population with little differences in attitudes between HSE users and non-users. However, evidence of HSE users focusing on HSE research more than non-HSE users, supported claims of the influence of HSE research on use. Non-HSE users rather focused on WPE research.

A central finding was widespread acceptance of research in the general responding population of HSE users and non-HSE users. Survey data showed that, of 78 replies to Question 9 (Appendix 12, p.247), a large majority of 80 % reported being trained in research analysis (Figure 6.6, below). Of 60 responses to Question 10b (Appendix 12, p.247), 92 % (n = 55) reported finding the training useful, with none reporting training being 'not useful' (Figure 6.7, below). In addition, there were no reports (Figure 6.8 below) of 'never' accessing research, with 78 % (n = 59) of 76 reporting accessing research weekly or monthly and 11 % (n = 8) reporting yearly access. There was only limited evidence for HSE users having a greater focus on research from these figures. No HSE users responded 'no' to being trained, but 13 % (n = 7) of 54 non = HSE users reported not being trained and 7 out of 8 'yearly' users of research (Question 11, Appendix 12, p.248) were non-users of HSE. Only one herbalist (non-HSE user) reported not being trained in research skills *and* limited (yearly) use of research.

In terms of how this training was delivered in Question 10 (Appendix 12, p. 247), 69 % (n = 42) of 61 responses stated that training was 'Part of formal herbalist training', with 25 % (n = 15)

stating 'other' which were detailed as through a university course and one 'through teaching on herbal courses'. A further 4 (6%) stated that training was through Continuing Professional Development.

There was also no evidence of any differences in reported use of research for members of the AMH and URHP for which there were no reported HSE users, compared to the NIMH and the CPP. Furthermore, looking at herbalists who attended non-BSc training courses, 5 out of 8 reported not being trained in research yet 6 reported at least weekly use of research. There was therefore no suggestion from the data that training in research analysis or affiliation with research (in PAs) is associated with increased use of research.

Figure 6.6 : Relative percentage of herbalists who reported being trained in research analysis (Question 9, Appendix 12, p. 247)

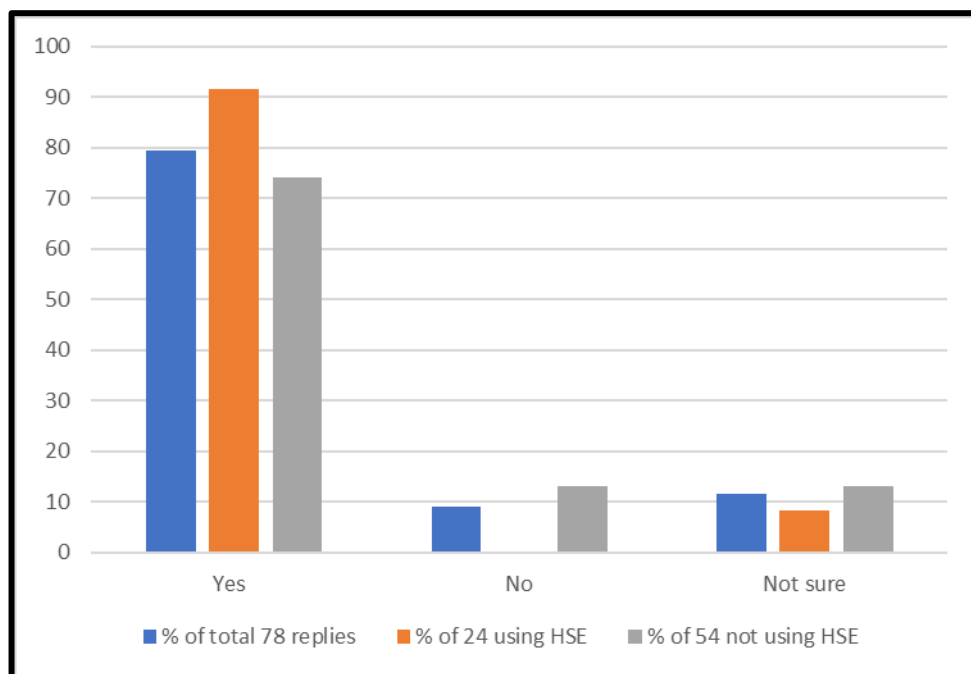


Figure 6.7: Relative percentage of herbalists who reported research analysis training was useful (Question 10b, Appendix 12, p. 247)

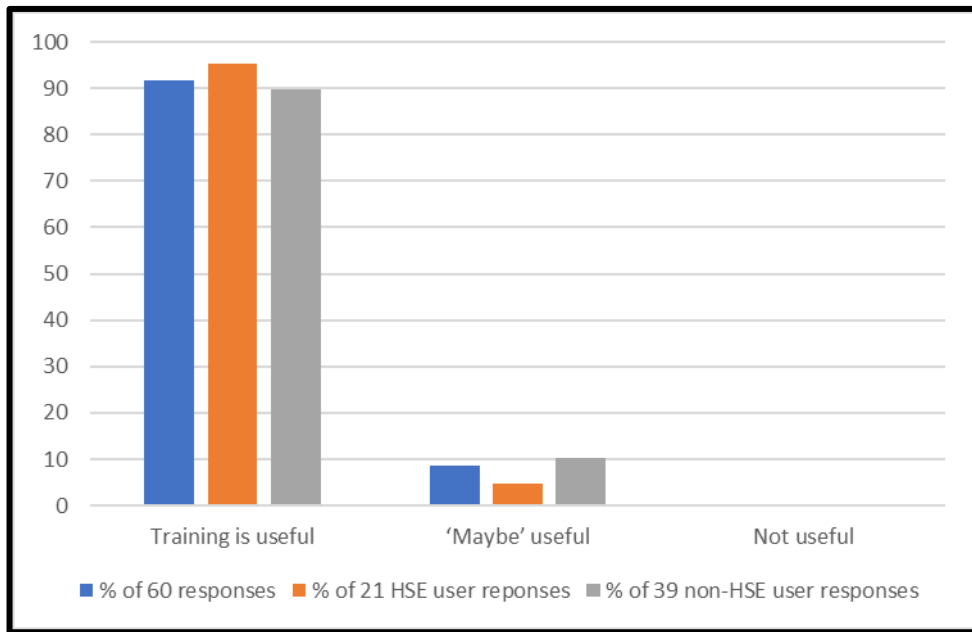
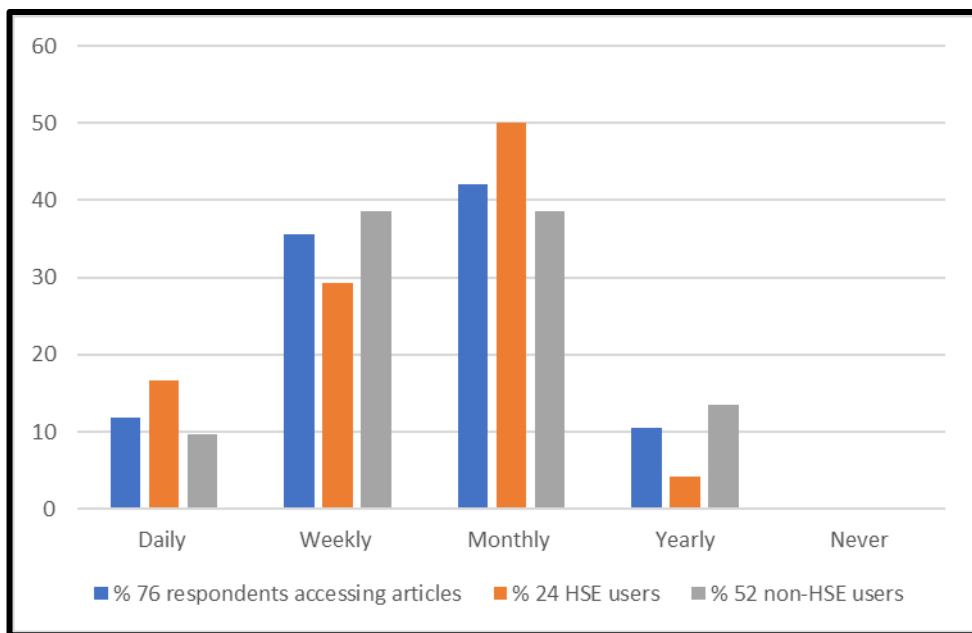


Figure 6.8 : 76 respondents stating frequency of access of research, analysed in terms of HSE users and non-users (Question 11, Appendix 12, p.248)



However, despite overwhelming reports of acceptance of research, survey comments from Q12a;b were all cautious. There were many comments below from non-HSE users indicating other uses for research than informing clinical decision-making, although one non-HSE user reported inclusion of a herb in a formula *'based on a paper suggesting potential benefit'*. Limited comments from HSE users indicated more influence on practice. Comments were:

Non-HSE users:

- *'only one part of the mosaic of knowledge. I use it to inform me, not necessarily guide my prescribing in a direct way'*
- *'I tend not to base my prescription on these studies, but I keep an eye on them. I would consider the research on standardized extracts, but would not necessarily expect the whole herb to be the same'*
- *'I read more papers than those that merely base their efficacy on standardised extracts'.*
- *'It often puts me off using that plant because it becomes more about constituents rather than synergy and the other aspects'*
- *'It depends on the study as a whole...Rather than just use the standardised extract, I would evaluate for myself...'*
- Research has a *'commercial impetus'*
- *'...interesting general information'*
- Research *'has not changed my use of plants'*
- *'When preparing to give a talk, the audience often like some evidence'*
- *'I like to be able to back up my choices with research...But I also believe that other herbs with little "research" have worked for thousands of years'*
- *'I find it frustrating as the testing models are often seemingly irrelevant to practice and then the outcome feels like it skews the perspective on the plant and its history of use'.*
- Use of research *'relating to safety'* or *'when a client asks me'*
- Use of research to *'back-up...what we already know through tradition'*
- *'Most ...articles I've tended to look at have been whole plant extracts...I tend to use them as guides rather than sticking strictly to the dosages in the studies'.*

HSE users were somewhat more positive but comments were limited:

- *'It depends on the quality of the study, and the particular indications of each patient'*
- *'Curcumin – lots of good research on this, but also on whole plant extracts – so I try to balance with use of both together'*
- *'I (use) a dose so that the active compound levels are at those similar or equivalent to the research'.*

A lack of comments about the clinical influence of research from non-HSE users reflects survey findings:

No. 2 discussed their relationship with research and ultimately finds it not useful or informative for practice:

'I'm more likely to listen to what other herbalists say or go to my books, materia medica (than follow the research)'.

They talked about reading research to add to their knowledge base and finding it a stimulus for looking at traditional evidence:

'but I might have an idea and go, 'oh they're looking at that, I wonder what prompted that', then I might look at some traditional views for that. I will occasionally, if I'm trying to justify something or if I have something that's new to me, or a new herb, I might have a look'

However No. 2 concluded with limitations on the usefulness of the research body and its lack of studies that reflect herbal practice:

'...but probably I'd reject a lot of the research, because it's HSE, because it's just animal testing, because it's looking at a disease and a herb rather than holistic treatment of herbal medicine, which is never a disease and a herb, so I'm quite quick to scan and reject that research anyway ...It's really rare to find a study setup that reflects holistic practice. You can't look at 'is hypericum useful in depression' and answer yes because it's like what depression? Depression is this huge big thing that affects almost everyone so there can't be one solution; we have to understand it on its layers and its depths and it's rare to see research that actually looks at the way we combine our prescribing, that looks at different types, be it constitutions or feelings we get, the kind of thought patterns that certain people have are very different to another'.

No. 2 further discussed how they were trained in use of research but that has since become less relevant in practice:

'I quite often use that sentence 'the research says' but it's irrelevant to me. When I was training, the idea was make herbal medicine talk the same language as the medical profession so we were noticed and accepted, whereas as time has progressed I don't want to be part of that really. Sometimes I do put that coat on and say words like 'the research suggests' or 'I read a recent study' but that is actually irrelevant to the way I practice.

In addition, No. 4 pointed out conflicting evidence in HSE research which may limit usefulness:

'There's piles of research on ginkgo saying it doesn't work and piles of research saying it does work; all that tells you is about research'

And No. 1 would like research to be more distanced from funding that may bias results:

'we all know about research agendas; can be profitable.... Like to hear more from independent researchers perhaps'

In contrast to the lack of positive comments concerning research above, it was found that there were many positive comments made by HSE users in interviews concerning the importance of research use. HSE users in interviews discussed the importance of using available research, but also being cautious, whereas non-HSE users were relatively 'negative' in their research-related comments. However this difference in comments may be related to characteristics of these HSE users being more experienced in HSE use. They may represent a minority of herbalists who are more positive about HSE and research.

No. 7 discussed how important use of research is to WHM practice, that herbalists need to adapt as new evidence evolves but that it needs to be integrated with traditional practice:

'we have to be adaptable don't we...we have to look at research, we have to interpret our practice in the light of new research that comes through but I really do feel that has to be balanced with our knowledge from traditional folklore, ethnobotanical use as well. I think it's not an either-or it's an AND; we have to integrate'

No. 11 suggested that it is wise to use what research is available and not dismiss it:

'Well I tend to use quite a lot of standardised extracts, erm, basically because I'm of the view that modern science gives us insightsand then obviously it's a bit poor of us not to bear that in mind in practice...we shouldn't really sweep aside what modern insights, what modern medicine, what modern science can teach us.....it's remiss not to'

No. 7 discussed the risks associated with attempting to integrate research with traditional practice and the issues of using research inappropriately:

'..the problem with research, particularly in a test tube, even animal models, probably not that relevant to humans so a compound that can be shown in a test tube to be useful probably isn't having an effect in the human as it's either destroyed in digestion process, has zero bioavailability or levels are too low to have any pharmacological relevance. So obviously with my (science) background, I think research is important but I think you have to interpret it very carefully....I think the problem is a lot of people don't necessarily do that they just see a bit of research that says that herb can be used to treat that and

they go ahead and use that without the knowledge; and they use a concentrated extract of that or a standardised extract, because that's what's used in the clinical trial and you know I think that's problematic, I would say, so I think, take on board the research but don't let just research shape your practice. I think it has to be a harmonisation between all uses. And other research as well; I would never base use on just the one piece of research because we know that as we know with research, if you plug everything in you can more or less pull out what you want to, to show what you want if you manipulate the data well enough. So you have to be cautious I would say'

No. 5, talked about how they use research in practice and find it useful:

'...writing up for a patient, I often do big work-ups for patients so....I'm looking at pharmacokinetics of the drugs they're on and then I'm building a picture of the herbs that are going to work with the drugs and that will lead me into lots of what's the research out there, what do we and don't we know so I do a lot of that'

No. 11 discussed how important it is to follow HSE studies with HSE products and that they believe many herbalists do not do this:

'..... to replicate those results it's only reasonable that you need to replicate the methods and also the extracts that were used ...An awful lot of people are probably pinning what they do with their ordinary tinctures has come from that standardised world, I'll put money on it.... They're making a mockery of what they're doing'

They also consider it strange that anyone would not follow the research, for example on *S. marianum*:

'...it's weird that I do not use milk thistle in anything less than 60 % extract but then you know, I mean for me it seems that anybody would (use it)'

No. 7 also echoes this need to follow HSE research with HSE products:

'...there are certain herbs that in practice I find just you can't get enough of in a tincture to actually replicate the clinical research sort of doses used so I would say here things like turmeric, Boswellia...G. biloba'

No. 7 also reported initially being drawn to using *C. longa* HSE due to the research evidence and has found Milk thistle HSE research useful:

'Just primarily, that was research led because the levels of turmeric that were very clearly shown to have a pharmacological effect were high.... There's quite good research on milk thistle as an antioxidant and anti-inflammatory but also having anticancer activity particularly against some non-small cell lung cancers'

No. 6 reported relying on research evidence for *G. biloba* HSE and finding HSE development interesting:

'if you're looking at Egb761 (G. biloba HSE) it's ...in the Maudsley hospital prescribing guidelines; it's actually in one of the supplements to the BNF..... it still does say that G. biloba might be used where other side effect medication effectively aren't working....I'd use it in terms of what the research says...that's the only one that's got evidence.... I think that's a fascinating field of research going forward really'

No. 6 also stated that they would use *G. biloba* HSE only for conditions indicated by research:

'I'd use it in terms of what the research says...(otherwise) I'd just go for a normal tincture'

In addition a survey statement recalled a seminar message that keeping up with HSE knowledge:

'the lecturer... said that herbalists need to be knowledgeable about standardised extracts otherwise they'll only be used by OTC companies and pharmacists...Medical herbalists are in the best place to use them safely ie. 'Qualified, and we see our patients regularly so can monitor properly'.

Looking further at differences between HSE users and non-users related to research, there was evidence of HSE users having a greater association with those PAs and training courses with a research focus. This suggests that they had a greater focus on, or more explicit training in use of research and increased affiliation with research or research-literacy compared to non-HSE users.

Concerning general research literacy, No. 6 questioned whether herbalists are generally research literate, also pointing out lack of research access that may hinder this:

'Of course what we don't have is a very accessible body of knowledgewell we do... if you have access to ... database(s) etc..... or necessarily the skills and knowledge to be able to (despite what our training aimed to encourage us to do)appraise carefully and thoroughly and with confidence – it's all very complicated'.

No. 6 also pointed out the lack of evidence from practice sharing or case study database:

'We haven't got into widely sharing - there is no national database of case studies'.

There was a noticeable difference between HSE users and non-users in terms of which PAs they were members of, as requested in Question 26 (Appendix 12, p. 250) (Table 6.7, below). Whereas 34 % of (n = 56) NIMH and 39 % of (n = 18) CPP members, taking part in the study, reported using HSE, no participating members of URH P (n = 7) or AMH (n = 5) reported use, although numbers of participants were limited for these latter PAs and there was only a limited 7% response rate for AMH.

Table 6.7: HSE use or considered use, related to PA membership (using data from Questions 6, 20 and 26, Appendix 12, pp. 246, 249, 250).

PA	Number of respondents / % of 73 *	No. using HSE / % of members	No. not using HSE / % of members	No. using or would consider use of HSE / % of members
NIMH	56 / 77 %	19 / 34 %	37 / 66 %	31 / 55 %
CCP	18 / 25 %	7 / 39 %	11 / 61 %	12 / 67 %
URHP	7 / 10 %	0	7 / 100 %	2 / 29 %
AMH	5 / 7 %	0	5 / 100 %	0

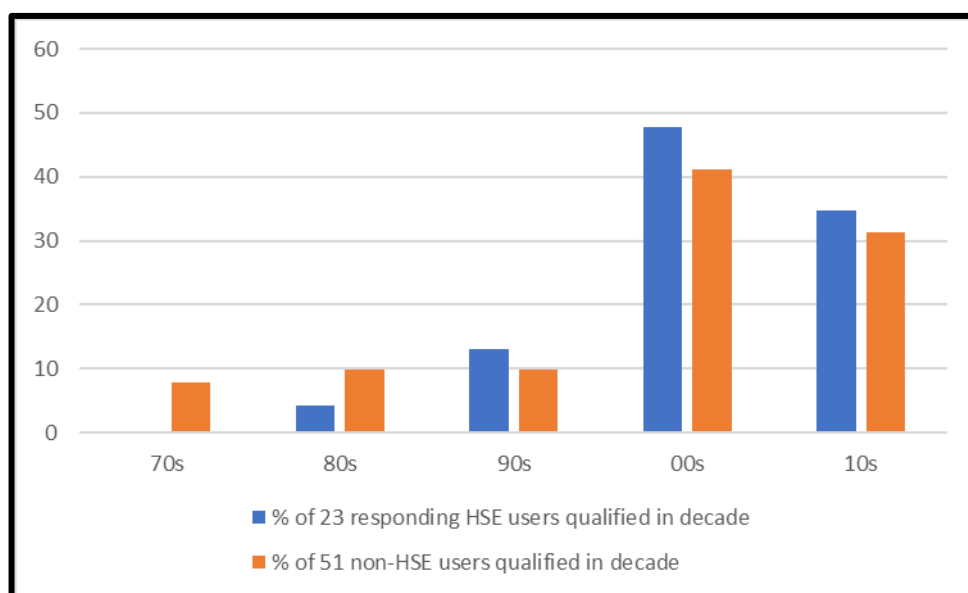
* n = 13 report being a member of 2 PAs

The stark difference in reported use between membership of PAs NIMH and CPP compared to AMH and URHP (Table 9) may be proposed to be related to PAs having different philosophies about practice. Evidence for different PAs' approaches to HSE and practice was taken from the 'about' sections on their websites. For CPP, with the highest percentage of HSE users, their statement about the importance of research is explicit and detailed. It explains how members' practice is based on research and TK, with seminars to support research use and an aim to integrate herbal and mainstream healthcare. The NIMH (2021a) states its mission as raising the professional standing of medical herbalists and although a primary focus on research is not stated, this implies an approach that integrates the modern world of research and may be reflected in HSE use findings. With the largest percentage of HSE users, it is not surprising that herbalists may be attracted to a CPP based on the fit between their attitudes towards research and that of the PA. This would seem more likely than herbalist members' attitudes being influenced by the PA, although this cannot be ruled out. In contrast, for those PAs where no members reported HSE use, there is no mention of modern practice or research. The United Register of Herbal Practitioners (URHP, 2021) focuses on the traditional 'vitalistic' approach

that does not find an obvious fit with modern biomedical research. The Association of Master Herbalists (AMH, 2021) reports only that training is based on the work of John Christopher, a 20th century American herbalist and his School of Natural Healing, which makes no reference to modern research (School of Natural Healing, n.d.).

Now looking at the influence of training courses, although there is little evidence for a link between HSE use and decade trained, the small minority of responding herbalists trained in the 70s and 80s were less likely to report HSE use. It may be very tentatively suggested that this is related to herbal training courses only introducing a focus on research in later years (see Appendix 14, Question 25 and Figure 6.9 below). The large majority of both HSE users (81 %) and non-users (72 %) reported qualifying this century.

Figure 6.9 : Percentage of HSE users and non-users in terms of decade qualified (Question 25, Appendix 12, p. 250).



Stronger evidence that training courses may influence HSE use is found in HSE users being more likely to have been trained in BSc university-accredited courses with a research methods focus. These herbalists are therefore considered more research-literate than others (although noting that those on non-BSc training courses were limited in number). Indeed there were no HSE users identified who had attended a 'non-university' training course (Table 6.8). Of 8 herbalists who attended non-BSc training courses, 5 reported that they were not trained in research (Table 6.8).

Table 6.8: Showing use of HSE or WPE depending on training course (Question 24, Appendix 12, p. 250)

Training School	Number attending school / % of 74 responding users	No. of HSE users attending school / % of responding 20 HSE users	No. of non-HSE users attending school / % of 54 responding non-HSE users
BSc training courses	66 / 89 %	20 / 100 %	46 / 85 %
College/school of Phytotherapy (accredited by University of Wales)	19 / 26 %	7 / 35 %	12 / 22 %
Middlesex University	10 / 14 %	3 / 15 %	7 / 13 %
Lincoln University	9 / 12 %	1 / 5 %	8 / 15 %
University of East London	8 / 11 %	3 / 15 %	5 / 10 %
University of Westminster	7 / 10 %	4 / 20 %	3 / 6 %
University of Central Lancashire	6 / 8 %	2 / 10 %	4 / 7 %
Leeds University	1 / 1 %	0	1 / 2 %
Scottish School of Herbal Medicine	6 / 8 %	0	6 / 11 %
Non-university training courses	8 / 11 %	0 / 0 %	8 / 15 %
NIMH	2 / 3 %	0	2 / 4 %
Self Heal School	2 / 3 %	0	2 / 4 %
International Register of Consultant Herbalists	1 / 1 %	0	1 / 4 %
Hydes School of Herbal Medicine	1 / 1 %	0	1 / 4 %
College of Naturopathic Medicine	1 / 1 %	0	1 / 4 %
Hein Zeylesta apprenticeship	1 / 1 %	0	1 / 4 %

There was some evidence from interviews of scientific background or training affecting HSE use although with no obvious conclusions. No. 4 stated: *'I think people's perspectives as herbalists depend upon your background and your training'*

No. 9 linked background training with use of HSE:

'with my training in chemistry and biochemistry and biomedical as well I'm not afraid to use concentrated supplements in the way they're used in clinical research papers'

No. 5 suggested a science-based background supports HSE use:

'I'm a College of Phytotherapy, very science-y graduate. We're all scientists'

However, No. 2 explained that going into WHM was a move to do something different:

'And I don't know how much is influenced from – I started in pharmacy so I was kind of like 'I don't want to do this'...I think as I was training, I felt that, 'cos I came from orthodox medicine, so obviously that's all about focusing in on tiny little actions and to me I was attracted to herbal medicine obviously because of its being holistic in nature. Erm so to me going down the standardised extract route always felt like a backwards step for me when I was trying to move forward'.

Similarly for No. 9: *'Considering my science background....I'm just not into ...(HSEs)'*

Survey findings above suggested that HSE users and non-users had a similar focus on research, but with HSE users being more likely to be trained in analysis and therefore more research-literate. Following this, differences were found in the data that suggested overt use of HSE research by HSE users compared to non-HSE users, with non-HSE users rather focusing on WPE research. These findings support the reported influence of research on HSE use. This data came from specific HSEs used and Question 12 (Appendix 12, p. 248) about most useful herbal research followed.

C. longa was the most reported HSE, by a long way. It has the strongest body of research evidence to support its use (Appendix 3) compared to other HSEs, as discussed in the introduction. This may suggest an influence of this most compelling HSE research on HSE use. The relatively reduced use of the other HSEs which also have large yet less compelling research bodies (*G. biloba* and *S. marianum*) may suggest an awareness of the research.

Question 12 asked about the preparation of herbs that herbalists use when reading and following studies that use HSE products. For example, after reading influential research on *C.*

longa HSE a herbalist might choose to use the HSE *C. longa*, as used in the study, or they might choose to use the WPE even though the evidence related only to the HSE. This use of WPE might be considered by some to be 'inappropriate' (Appendix 14, Question 12a). All (n = 51) responding non-HSE users reported using WPE preparations in practice when using research based on the HSE. Of 24 HSE users, 63 % (n = 15) respondents reported using the HSE some or all of the time, when following HSE studies and 36 % (n = 9) reported that they would use the WPE instead. 25 % of HSE users (n = 6) reported *only* using the HSE product following HSE studies (all of these referred to the use of *C. longa* HSE). Only 8% (n = 2 of 24) of responding HSE users reported following HSE studies all of the time *and* also reported using more than 1 HSE based on these studies. It appears that a majority of HSE users reported being influenced by HSE research to use HSE preparations.

Question 12b (Appendix 12, p.248) which asked for 'most useful' herb research offered evidence for the preferential focus on HSE research by HSE users and of WPE research by non-HSE users. In terms of general research that respondents find most useful (Appendix 14, Question 12b), HSE users were more likely to state research on HSE herbs as useful. 80 % (n = 20) of 25 herb mentions from HSE users were herbs defined as HSE in this study (stated by 86 % (n = 12) of 14 HSE users responding to Question 12b). In contrast, non-HSE users were more likely to state non-HSE herbs; only 25 % (n = 12) out of 48 mentions were HSE herbs (stated by 32 % (n = 10) of 31 non-HSE users) (see Appendix 14, Question 12b). In addition, 32% (n = 10 out of 31) non-HSE users reported HSE herbs as most useful research, again suggesting 'inappropriate' use.

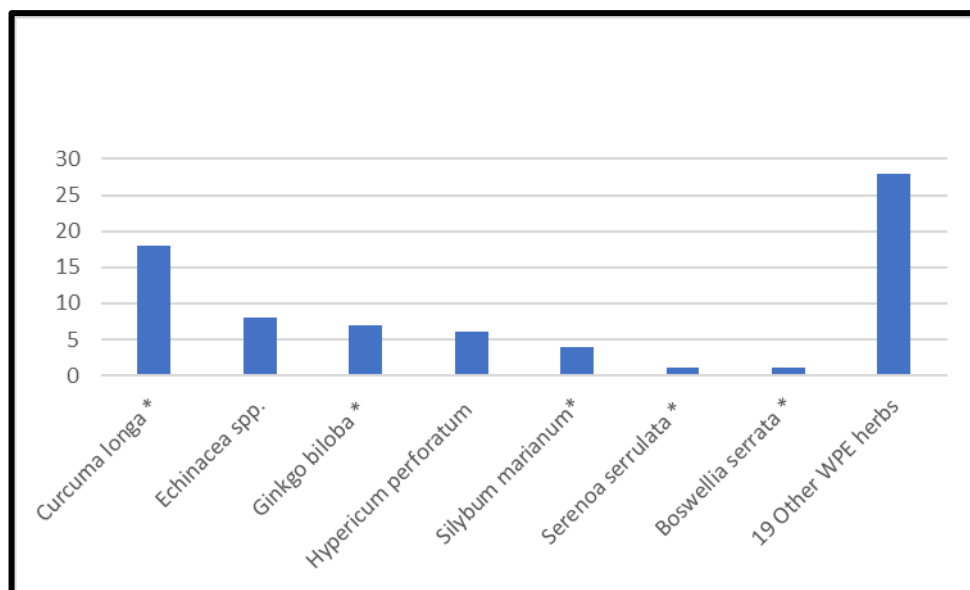
Further detail about Question 12b is as follows. 65 responses were obtained out of the 78 participants. Although the question asked for the 'most useful herb', multiple answers were often given and included in the analysis to indicate which herbal research is foremost in herbalists' minds. Of 45 respondents who specified individual herbs as most useful research, 26 herb examples were given, of which 21 were WPE herbs (Appendix 14, Question 12b). WPE herbs had a total of 43 mentions made and HSE herbs had 30 mentions. Out of the 65 responses, 11 herbalists reported that they found research on *many* herbs useful without specifying which, therefore a total of 56 herbalists (86% of 65 responses) indicated that they found plant research useful. The remaining 14 % (n = 9) of 64 responses stated that they did not find any specific plant research useful. However, this may be that they rather found no specific herbal research most useful out of that which they use. This is evidenced by 7 of these 9 respondents reported accessing research articles weekly/monthly and finding training in research useful. For the remaining 2 who reported accessing articles yearly they also reported being 'unsure' about being trained and usefulness of training. Both HSE users and non-users

stated between 1-2 herbs on average (HSE users stated an average of 1.8 herbs; non-SE users 1.5 herbs) and there was no indication that either HSE users or non-users were more likely to state multiple herbs, therefore skewing the results (Appendix 14, Question 12b Chart).

Considering specific herbs stated as most useful (see Figure 6.10 and Table 6.9 below), *C. longa* was the most popular with 25 % (n = 18) of 73 total mentions and 40 % of 45 responding herbalists mentioning it. However when comparing HSE users and non-users, 71 % (n = 10) of 14 HSE users mentioned it, compared to only 26 % (n = 8) of 31 non-HSE users, reflecting the increased focus on HSE research by HSE users above. The next most popular herb was Echinacea with 11 % (n = 8) of total mentions and 18 % of 45 responding stating it as useful research, split into 14 % (n = 2) of 14 HSE users and 19 % (n = 6) of 31 non-HSE users. Other popular herbs were (in order) *G. biloba*, *Hypericum perforatum* and *S. marianum*.

Evidence has been outlined that supports claims of the influence of HSE research on HSE use. Awareness and use of research by non-HSE users is supported by *C longa*, being by far the most popular herb over all. It has the most compelling body of research evidence. However, this may suggest ‘inappropriate’ use of HSE research to support WPE use, as introduced above. The most widely stated WPE herbal research used have amongst the largest bodies of research available (Table 3.1) (namely *Echinacea* spp. and *H. perforatum*). This suggests that non-HSE users are at least aware of the research bodies.

Figure 6.10: Summary of most useful herbal research reported - number of mentions by 45 responding herbalists (Question 12, Appendix 12, p. 248).



* HSE herbs

Table 6.9 : Summary of most useful reported herbal research by HSE users and non-users (Question 12b, Appendix 12, p.248).

Name of frequently mentioned herb research	Number of mentions / % of total 73 mentions	% of 45 responding mentioning herb	Mentions by 14 HSE users / % of 14 HSE users	Mentions by 31 non-HSE users / % of 31 non-HSE users
<i>C. longa</i> *	18 / 25 %	40 %	10 / 71 %	8 / 26 %
<i>Echinacea</i> spp.	8 / 11 %	18 %	2 / 14 %	6 / 19 %
<i>G. biloba</i> *	7 / 10 %	16 %	3 / 21 %	4 / 13 %
<i>H. perforatum</i>	6 / 8 %	13 %	1 / 7 %	5 / 16 %
<i>S. marianum</i> *	4 / 6 %	11 %	4 / 29 %	0

. * Herbs that are identified in this study as HSE herbs

6.3.4.2 Data concerning evidence from herbalists' own practice and 'strength' of HSE

The results now move on from the use of research to evidence from herbalists' own practice and the importance of 'strong' attributes of HSE. There was little direct evidence of reported effectiveness in practice but more reported on the need for the 'strength' of the HSE, particularly in serious conditions.

In terms of effectiveness, only No. 5 reported finding *C. longa* HSE regularly very effective in practice, and is one of their most useful medicines:

'...I find it very effective....what happens most people who are getting a bit older and stiff in the joints, it's one of the first things I give them –it's what I start with....and most of them will come back within a week or 2 and go my god I feel 20 years younger....If I only had 20 things to practice with it would definitely be one of them'.

No. 5 also reported finding *C. longa* HSE very useful when a large dose is needed for cancer support:

'I do a lot of cancer support so they might be on a turmeric extract....if I want big regular doses I put them on a Lamberts, 2 g or 1g'

No. 10 discussed use of *S. marianum* HSE to get a high enough dose:

'I would use tincture but the tinctures are high alcohol – when you're thinking of the equivalent of 14.7 g then I might give either 1 or 2 of those at night – 1

of those at night would equate to 100ml of a 1:1 and that's a lot of alcohol. So that's why I choose that...'

No. 7 reported working a lot with cancer patients and found HSE necessary to get a big enough clinical dose:

'I deal a lot with cancer patients....there are certain herbs that in practice I find just you can't get enough of in a tincture to actually replicate the clinical research sort of doses used so I would say here things like turmeric, Boswellia...G. biloba I tend to use concentrated tablets...where I really want a very big G. biloba hit then I'll use 2,3, sometime 4 tablets of G. biloba just to get that antioxidant etc level up there...(and with S. marianum) you need quite high doses, so rather than get somebody slurping whole loads of milk thistle as a simple I use the concentrated extract that's extremely high silymarin so they can take 3 tablets of that and they're getting an equivalent of a huge dose of silymarin.....if someone's taking ...a huge dose of turmeric, it will arrest and keep the myeloma stable...(with) C. longa tincture there's absolutely no way it's going to have any effect on the myeloma at all but....there's a lot of clinical research to actually show that...'

No. 12 also reported using HSE for serious conditions when a high dose is required:

'There are times when I would think OK if I need a really high dose, then maybe I would consider curcumin as an extract, maybe in the case of cancer or inflammatory disordershappy and comfortable to use those ...when it comes to conditions such as those I've just described...'

No. 6 also discussed use of C. longa HSE if a high dose is required:

'(if there is)...evidence to suggest that you're not going to be able to get enough of something - if you're going to need a lot of tincture - too much really.... to get the appropriate dose'

and No. 6 also discussed use of G. biloba HSE given a 'good reason' for use in a serious condition:

'I would go for EGb761 – that's the only one that's got evidence...with schizophrenia....(for other less serious conditions) I'd just go for a normal tincture...I tend not to favour standardised extracts unless there is some particular reason to say well although I don't routinely use them there might a

particularly good reason to use them...I think if I said I don't use them I'd be missing something helpful'

Non-SE users similarly reported that they would consider HSE in situations where a high dose was required or a condition was serious:

No. 1 discussed HSE *C. longa* in serious conditions:

'Curcumin is difficult to take in sufficient doses unless as standardised extract....(it's) easier to take, rather than overloading, particularly in serious conditions that might need a lot of interventions....I think (NAMED HERBALIST) when he says in a lecture some years ago and I think he thought of advocating use of standardised extracts to get enough curcumin down someone's throat'

No. 2 said that they understand how a large HSE dose may be needed for achieving quick change and may be preferable to pharmaceuticals:

'when we're running out of time, I would be willing to use something that had been demonstrated to be more potent in that specific condition...I do appreciate that (concerning influential herbalists using HSE in serious conditions) they are trying to achieve a bigger change in a shorter amount of time, because time is of the essence... and I would say that when you're looking at the options of do we use a potent standardised extract or do we use a potent pharmaceutical or a combination of them both....the potent standardised extract is a better option than something that's potentially going to be toxic...(and)... if I need this very specific action in this very specific disease process and I'm willing to accept any consequences and side effects, then yes'.

No. 13 reported that they would consider HSE in serious illness:

'I think it depends what you're treating. A lot of these studies, if you look at turmeric for example, in respect of cancer treatment, or if you look at G. biloba in respect of dementia treatment or advanced cardiovascular events, then you are into treating serious illness.... in the majority of cases in herbal medicine we're not dealing with illness at that level of severity.....then why would you need to use something that hefty.... if I had a patient who was dealing with an aggressive cancer and they wanted to throw everything they could get at it, then yes I would be looking at the research, the standardised extracts'

Similarly No. 1 reported that they would use *C. longa* HSE if necessary:

'Possibly for cancer treatment, merely because it was recommended at a professional seminar run by NIMH... There may be times when standardised extracts are appropriate, particularly when the strength of the thing, curcumin comes to mind, but even then I'm not massively sold on it... for someone who is very seriously ill I'd suggest it.... easier to take (C. longa HSE), rather than overloading, particularly in serious conditions that might need a lot of interventions'

No. 9 echoed this use in cancer:

'if I worked with cancer a lot maybe it would be very different, if you have to get somebody better really quickly - maybe I might.... So it's not something that I've ever really done but if I had to I think potentially I might opt for a standardised extract for that, maybe until I judged that you're turning a corner maybe, I really don't know.

No. 13 also reported that they would use HSE if they treated serious illness:

'So somebody like (NAMED HERBALIST), he treats a lot of people who have cancer and uses a lot of standardised turmeric...if I was doing that, I probably would be doing that too...I haven't ever specialised in serious illness, partly because it just hasn't happened, I haven't had a particular feeling that I wanted to do that... but if I were then yes I'm sure I would be using more standardised extracts'.

There is also limited evidence, from interviews and survey questions 14 to 17, that herbalists have directly compared WPE to HSE in practice and found in favour of both in different circumstances. This was stated in a survey response: *'Both... (WPE and HSE)... C. longa (are) useful in different clinical contexts after comparisons'*. From the survey data, it seems such direct comparisons are not often carried out. This is not surprising since it is difficult to achieve in practice and one survey reply suggests *'I doubt anyone does a quantitative intraindividual comparison'*. Comparison also requires a busy practice and No. 5 stated: *'Most people....don't practice very much; they don't have a lot of experience....my survey (found)....that for most people it was their hobby'*. It is also possible that herbalists did not understand the question if this is not something that herbalists pay attention to in practice.

In terms of instances where HSE was found to be preferable to the WPE, there were 4 respondents in the survey (17 % of HSE users) who reported that they had compared HSE to WPE and found HSE preferable. *C. longa* HSE, *S. marianum* HSE and *Boswellia serrata* HSE

being found preferable in cancer and *G. biloba* HSE for cerebral circulation (see Table 6.10,p. 141).

Interview data also offered evidence of comparison.

No. 12 reported experience of adding *S. marianum* HSE to a prescription containing *S. marianum* WPE with good effect in reducing iron overload:

'I introduced the...(HSE)... alongside it and that's when his iron levels began to decrease'.

No. 7 has a busy practice, treating people with cancer, and discussed directly comparing a WPE and HSE in practice, finding the HSE preferable:

'Undoubtedly better results. You can see a huge difference'I just know from experience that if I'm trying to treat somebody with say myeloma if I give a turmeric tincture there's absolutely no way it's going to have any effect on the myeloma at all but if I eat a tablet or capsule extract, where one capsule is equivalent to about 5g of pure turmeric spice, if someone's taking 12 of those, a huge dose of turmeric, it will arrest and keep the myeloma stable – there's a lot of clinical research to actually show that and it's widely accepted now that turmeric can be used.

No. 7 explained how the comparison between HSE and WPE happened little by little:

'...pure trial and error, using tinctures in my patients, monitoring results and tumour markers, and seeing no effect with turmeric tinctures'

Table 6.10 : Table to show details of survey reports from 7 respondents about comparison of HSE/WPE in clinical practice (Question 17, Appendix 12, p. 249).

	Comment about comparison
4 HSE users (16.7 % of n=24):	‘Therapeutic outcomes (in cancer cases) tend to be superior’ with HSE Boswellia, S. and C. ‘to ensure delivery of larger amounts of active constituents, which would be hard to do via tinctures alone’.
	‘Curcumin as a standardised product was readily absorbed’
	Both WPE and HSE <i>C. longa</i> useful in ‘different clinical contexts’ after comparisons.
	HSE <i>G. biloba</i> was found more effective than tincture for supporting cerebral circulation: ‘had previously used whole plant extract (tincture) which had been helpful but evidence proved clearer with standardised extract’
3 non-HSE users (5.6 % of n=54):	‘(<i>C. longa</i> (WPE)... more rounded action, fewer side effects’
	‘ <i>C. longa</i> (WPE)...patients found their joints were less achy’;
	‘patients report better clinical outcomes with whole herb <i>C. longa</i> capsules (in combination with trikatu and boswellia), as opposed to Lamberts Healthcare 95 % standardised <i>C.</i> extract.

6.3.4.3 The influence of other herbalists on HSE use

Following the strongest factors of research and evidence from own practice in Question 7 (Appendix 12, p. 246), the reported strong influence of other herbalists and herbalist seminars is also supported by further informative data. There is evidence from interviews and survey

data that a limited number of experienced herbalists have historically been influential on others and their views of HSE.

Evidence from interviews and the survey suggest an influence of respected herbalists who use HSE, both for current HSE users and also non-HSE users who have since stopped using HSE:

No. 12, who uses HSE, discussed the positive influence on HSE use from seminars and individual recommendation:

'...seminars by people like (NAMED HERBALISTS)...they use highly standardised extracts....when they're treating people with cancer. And I know particularly, because I did a peer consultation with Jonathan...and he was recommending quite highly standardised extracts so I was happy and comfortable to use those then and I think I probably still am when it comes to conditions such as those I've just described, so maybe cancer or extreme inflammation, possibly autoimmunity...I also find (NAMED HERBALISTS) ...very influential'

Survey data also showed evidence for the influence of respected herbalist in current use of HSE:

'I used to be wary of extracts but not so much now. I attended a post grad seminar on cancer treatment; standardised extracts were advised as part of protocols to provide robust treatment. The lecturer said "big disease requires big medicine".'

'...I was influenced by him (NAMED HERBALIST) and so that (curcumin) was the only one I've used'

Other non-HSE users describe being influenced in the past but do not use HSE currently. No. 1 who does not use HSE said that they would give weight to recommendations for HSE *C. longa* use from other experienced herbalists *'who have a practical record in a certain area (cancer)'* and would *'quote'* those herbalists and *'let the patient decide'*. No. 1 also pointed out that they would trust another herbalist's recommendation compared to supplement companies as they are *'not plugging an agenda for supplements'*.

No. 8, who does not use HSE, also reported being influenced by other experienced herbalist:

'I look at what other people do, say in the cancer area - if it helps that patient then I'll probably copy that'.

No. 10, a non-HSE user, was influenced in the use of HSE *C. longa* after attending a seminar by another herbalist but has since stopped using it:

'.....I was influenced by, when I was starting out working with people who have cancer – and I was asking experienced colleagues what they thought and (NAMED HERBALIST) ...advised me to use turmeric that was standardised to 95 % curcumin...'

Similarly, before arriving at their own decision not to use HSE from clinical evidence, No. 9 was influenced by such seminars:

'I'd been to a lot of (NAMED HERBALIST)' talks and the like and all the strengthened stuff and certainly (NAMED HERBALIST) and all cancers and you want to have all the strengthened....so I was in two minds initially' 'I've got a tremendous faith in (NAMED HERBALIST), he's way ahead of anything, he's years ahead of us and I've got a tremendous respect and I've been to loads of his lectures so that's why I was so openminded because of him'

No. 2 was also influenced to use HSE by another herbalist who recommended *C. longa* HSE, although they no longer use it:

'And that was because another herbalist who'd survived breast cancer told me that (curcumin) was the bees knees...I respond to talking to someone I trust'.

6.3.4.4 Minor factors in choice of HSE

Finally the report on how herbalists have come to use HSE considers less frequently reported influences on HSE use than the major factors above. The influence of supplement company seminars was limited in the current study compared to the major influences above. There was also only little mention of the consistency of HSE products in interviews and none in the survey.

Other minor factors in choice of HSE were limited to influence of supplement company seminars, quality and consistency. Influence of supplement company seminars was reported in the survey only; the issues of quality and consistency were reported in interviews only.

No. 8 worried about the quality of WPE:

'...(HSEs give)....consistently reliable results....I have no idea if I'm getting what I should be getting from an herb. So quality is the big issue; it worries me every time I dispense'

And No. 11 stated:

'It's one way that modern science has actually given us an insight to be able to give consistently reliable extracts'

And No. 5:

'I do it (use HSE) because I know it's standardised'.

No. 7 discussed *G. biloba* specifically as needing to be standardised in terms of natural fluctuations in active constituents:

'Ginkgo, there's a lot of evidence to suggest they have to be quite standardised or concentrated, erm, to bring them up to the right level of the bilobalides etc because again there's such a huge variability in levels of bilobalides, mainly I think because a lot of producers aren't aware that the ginkgo has to be picked in the autumn when the leaves are going yellow; if it's picked too early the bilobalides are just not there, so I think that's one of the issues'.

Another minor reason for HSE use also may be related to little overt reason. Although based on research reasons for using HSE may also be less than 'logical' and in interviews herbalists suggested that they haven't really given much thought to the issue before:

No. 11 suggested that they may return to using WPE given the stimulation to think about the issue:

'it's interesting, I haven't had this conversation before, oddly enough after 20-odd years, it's fascinating because the thing is I do find myself using an awful lot of standardised extracts. I'll be honest with you, perhaps I'll go back to doing that (using WPE)'

No. 12 reported not thinking very much about reasons for HSE use:

'I didn't really used to think about, too much about whether something was standardised or not and if there were times that I thought I needed something in higher dose I would use a standardised extract and not worry too much about it...'

No. 3 also suggested that reasons for HSE use may also be somewhat 'weak':

'I think you're going to find the answers pretty random – maybe a friend found a good one so they carry on using that, another one they found themselves because it worked on them'.

Finally 'other' reasons for HSE use given by 17 % (n = 4) of HSE users in Question 7 (Appendix 12, p.246) were '*Curcumin used alongside whole C. longa tincture or powder - benefits to both*'; '*dose determination*'; '*useful alternative to tinctures*'; '*...support of oncology*

patients...to...produce scientific evidence....in hospitals...'. None of these 'other' answers were given alone. It is also noted that no relationship was found between HSE use and busyness of practice (Appendix 14, Question 23) suggesting that experience is not a factor in HSE use.

6.4 Results address the first two aims of the study: HSE use is a balance of 'promoting' and 'opposing' factors

A summary of the results above may justify the claim that the first two aims of the study have been achieved. These are investigating how herbalists have come to use 'highly standardised extracts' (HSEs) and how widespread this practice is. It is proposed that a large minority of herbalists here have come to use largely individual HSEs in practice as a result of a balance between facilitating and opposing factors, at least some of which are identified here. They are included in Appendix 17 that represents the wider theory surrounding HSE use. Results offer a relatively uniform picture concerning identified characteristics of HSE users and non-users.

Directly 'promoting' factors that may encourage HSE adoption are shown in orange boxes in Appendix 17. Those that are reported as leading directly to use are the strong influence of clinical evidence from practice that followed recommendations from other herbalists and the research body. HSE use is associated with a history of training in research analysis in BSc herbalist courses and membership of PAs that focus on research. There is also some evidence of 'inappropriate' use of HSE research that suggests variable research-literacy. Reports of widespread, 'useful' training in research analysis reflects other 'facilitating' influences which are 'open-mindedness' towards HSE, lack of strong feelings, reduced historical controversy and clarity of choice.

'Opposing' factors shown in pink boxes suggest reasons why widespread use is largely limited to one HSE only. The most common reported HSE by far, *C. longa*, has the most compelling body of research. The strongest opposing factor identified is the focus on the natural WPE. There is also some remaining controversy, and lack of open-mindedness in the large minority of respondents. Reported use of research by all non-HSE users is largely focused on WPE studies which therefore does not encourage HSE. These influences are all proposed to lead to the widespread useful, clear use of individual HSEs (largely *C. longa*), with the general use of only one example limiting the challenge to the central WPE focus.

6.5 Reflexivity

It was important to consider the author's attitude, and changes in this attitude, throughout the study, in order to be aware of influences on study outcomes. This is specifically pertinent in this study given the aim of an objective methodology in CGGT, the justification for which was explained in the methods section. Records of the author's changing attitudes towards, and

therefore possible influence on, the study throughout data collection and analysis, were collected through memo-ing.

Although the author, as a herbalist, shared a wide range of beliefs and knowledge with those researched, and this was a benefit for collection and analysis of data, there were nevertheless differences between attitudes of the researcher and researched. These are important to investigate in order to further understand their influence and challenges to the objectivist CGGT methodology.

As outlined in section 5.3, the author's 'scientific' background and subsequent herbal training led to somewhat of a conflict in use of HSE. This initial lack of clarity and conflict about HSE use remained throughout the collection and analysis of interview data. Although this was not resolved, the centrality of this question to the author was modified as analysis continued. The lack of clarity was a bias that the author was aware of having a potential influence in interviews. This was limited by the open nature of the interviews and lack of additional questioning from the author. This lack of use of support questions may have been related to low confidence in interviewing as the researcher was a novice in this area but this was not considered an issue given the objectivist approach. Considering the attitude of the author further during interviews, they noted that, although still lacking clarity about the topic, they aligned their position with the interviewees. This may have been related to that lack of clarity. In seeking to understand each interviewee's position the author noticed that they agreed with all the positions taken by the interviewees in turn. The author had not been aware of being so readily influenced before this. In effect the author's bias was changed depending on the interview and this is not considered to have exerted any unwanted influence on the collection of interview data.

Although the author's initial question about lack of clarity in choice of preparation was not resolved, the centrality of the question became less important to the author as analysis of the data continued. Having initially approached the central study question of HSE use from the perspective of looking for 'answers' to the choice of HSE or WPE, as analysis of the data progressed, the author's attitude towards the survey question changed. Rather than finding any new 'answers' to the question of choice of preparation, the author rather found a wider developing descriptive picture of the relationship of herbalists with this issue. Possibly, due to coming from a scientific background, the author was looking for 'answers' where there were none found readily, and rather found a more descriptive picture of the relationship between herbalists and HSE.

Chapter 7: Discussion

The discussion below uses results and supporting literature to propose a picture of the responding herbalists in a wider context concerning their relationship with whole plant extracts (WPEs), highly standardised extracts (HSEs) and use of modern research studies. Data is informative in offering some additional description and insight into the relatively little documented, loosely defined ‘mass of tensions’ that many believe characterises Western Herbal Medicine (WHM) (Waddell, 2016; Bone, 2021; Nissen, 2010; Jackson-Main, 2005; Niemeyer et al., 2013; UK Parliament, 2021b). It is acknowledged that discussion and conclusions proposed here are limited due to the response bias associated with the limited response rate.

Results presented in Chapter 6 have addressed the first two aims of the study, understanding how herbalists have come to use HSE and how widespread this is, as summarised in section 6.4. Aim three, promoting discussion is addressed later in the implications section (8.3) and it is hoped that the reviews of the main HSE herbs in Chapter 3 may be informative. The discussion below takes these findings and places them in a wider context concerning the debate about the ‘modernising’ integration of research-based evidence with Traditional Knowledge (TK). This was introduced in Chapter two. The subject of the present study is central to this issue as it concerns research-based HSE and TK-informed WPE. An outline of this proposal is presented in section 7.1 and this is then expanded on in sections 7.2-4. Finally there is a discussion of the methodology and methods in terms of strengths, weaknesses and proposed improvements.

7.1 Placing the responding population in a wider context of integration between research-based evidence and TK

Data concerning the factors directly affecting (limited) HSE use has been presented in the results section, according to the first two aims of the study. Further to this, findings offer a wider understanding of the responding population that informs the important debate concerning ‘integration’ of research-based evidence (characterising the EBM approach) with TK in WHM populations across the world (Conway, 2005; Griggs, 1997; Evans, 2008; Wahlberg, 2008; Snow, 2016; Jagtenberg & Evans, 2003, Nissen & Evans, 2012, Niemeyer et al., 2013). Such integration has been proposed by Bone (2021) as necessary for ‘modernising’ the profession, was called for by Niemeyer (2013), predicted by Conway (2005) and suggested by Waddell (2008). Singer & Fisher (2007) noted that this process of blending seemingly opposing philosophies (based on modern science and TK) is a skill of herbalists. This was discussed in Chapter 2. ‘Integration’ of research and TK in the context of this discussion is understood to

represent the use of research evidence in a clinically useful way to inform WHM practice that is largely based on TK.

The picture here suggests a strong focus on the 'natural' WPE, but yet with the whole responding population reporting engagement with research studies. This may initially appear to represent 'integration' or 'normalization' of modern research-based methods within a practice based on WPEs and TK, as suggested by Waddell (2016) and Wahlberg (2008). Use may have been encouraged by the recent rapid increase in herbal RCTs, particularly concerning WPEs that reflect the central WPE focus, rather than training in research methods. Reported use of research from all participants contrasts with previous literature that had suggested more limited engagement (Nissen, 2015; Waddell, 2016; Sprung, 2016). Research appears to be utilised in two contrasting ways. The first way is represented by the HSE-using minority reporting engagement with research to appropriately and clearly support clinical prescription, largely of a single research-based HSE. This is considered to suggest 'meaningful', but limited, 'integration' of research-based evidence in a practice based on TK and WPE. This had been predicted as a consequence of training in research methods (Conway, 2005), as identified in the current data where HSE users were more likely to report such training. Relatively greater integration is suggested in the small minority of respondents who were more 'positive' about HSE and reflected in non-UK countries where WHM is practiced. The impetus to adopt the research-based scientific approach in countries such as Australia, New Zealand and Canada has been stronger than in the UK. WHM practice in these countries is associated with more research-based herbal products, the use of which is supported by this evidence base rather than TK. Reliance on such products may be associated with reduced focus on the natural WPE, as identified in survey data here. The second way of using research is represented by the large majority of the population engaging with research studies for non-clinical reasons of 'interest' and facilitating the decades-long aim of 'professionalisation' and engagement in the 'modern' scientific world; this was discussed in Chapter 2. Despite engagement with research, it is proposed that this evidence base is not 'needed' for informing the use of WPE, which is rather based on evidence from TK. This appears to 'by-pass' the issue of historical controversy of research methods as applied to practice (as introduced in Chapter 2), but there is also no evidence from the data that general objections remain. Lack of such historical controversy is proposed to be due to engagement with research methods not 'challenging' the central focus on the natural WPE, unlike use of the more controversial HSE. A current lack of identified objection to research methods in this study contrasts with continuing questions in conventional healthcare about the EBM approach that relies on RCT evidence (as discussed in 2.1); it is not clear how aware herbalists are of these ongoing issues.

The discussion below first addresses the central focus of the 'natural' WPE, associated with TK philosophy (section 7.2) and explanations are considered. The discussion then moves on to how this WPE focus is proposed to limit HSE use and meaningful 'integration' of research into a TK-based practice (section 7.3). A proposal for how herbalists have come to be engaged with research is outlined, followed by evidence and suggested explanation for only limited 'integration'. Suggested 'inappropriate' use of HSE research and associated variable research-literacy is then considered. This is followed by a closer look at the meaning of integration. Finally a summary of the discussion is offered (section 7.4) and Appendix 17 offers a flow chart of all study findings.

7.2 The central focus on the WPE

The focus on the 'natural' WPE was strongly stated by the large majority of survey respondents, including some HSE users. This is important for informing the debate around 'integration' of research-based evidence and TK as the philosophy of TK is associated with use of the 'natural' WPE. TK was introduced in Chapter 1. It is typically 'non-scientific' in a modern sense, experiential and accumulates over time (Niemeyer et al., 2013); it contrasts with modern scientific research-based knowledge that has a greater association with HSEs and other standardised research-based proprietary herbal preparations such as those produced by Lamberts Healthcare Ltd. (2021e). As discussed in Chapter 1 there is little evidence of reliance on such proprietary preparations in UK WHM, with herbalists' suppliers typically stocking relatively unprocessed 'natural' WPE.

The section below first considers the strength of this WPE focus. It builds on previous published reports of similar attitudes and reflects traditional WHM practice. A proposed recent renewal of this focus may be associated with end of the 'modernising' UK drive towards professional regulation (section 7.2.1). Another factor that may underly the strength of this focus is the relatively diverse philosophy of WHM compared to other herbal traditions such as Traditional Chinese Medicine (TCM) and Ayurveda (section 7.2.2). These issues are discussed below.

7.2.1 Strong and possibly renewed focus on the 'natural' WPE

Survey responses concerning reasons for not using HSE (from non-HSE users and volunteered by some HSE users), were strongly focused on the use of the 'natural' WPE. This is discussed below, starting with how it builds on previous studies and may have been recently 'renewed' after the end of the drive towards professional regulation in 2015 (Walker, 2015). There is no indication of a similar position in other countries where WHM is practiced, with the regulatory impetus increasing the attention to research and research-based products. Finally additional evidence from the survey that supports this proposed strength of focus are discussed.

This finding builds in a more representative way (through the survey), on previous interview studies that found a non-scientific approach in UK WHM (Wahlberg, 2008; VanMarie, 2002), specifically 'naturalness' (Nissen, 2015) and 'enchantment' with herbs (Waddell, 2016). Nissen (2010) reported that no surveyed herbalists described themselves as 'phytotherapists' and its association with research-based products, rather preferring titles related to the less overtly scientific 'herbalist'.

There is some evidence suggesting a renewed focus on the WPE since the end of the regulatory drive in 2015 (Walker, 2015). Bitcon et al. (2015) who studied a minority of herbalists who had strong focus on the natural WPE and rejection of 'products' such as HSE; they were considered to be 'different' from other herbalists. The authors concluded that '*... traditional knowledge, plant identification and simple herbal medicine preparation (are) redundant for many contemporary herbalists*' (p.110), due, in the view of those authors, to relatively industrial-scale WPE medicine manufacture taking herbalists away from the herbs (as suggested by Waddell (2016). Although this study does not inform all these specific issues raised by Bitcon et al. (2015) it does nevertheless suggest that there is not widespread abandonment of TK and the natural WPE. Those herbalists may now have more in common with respondents in the current study, suggesting an increased focus on the WPE since this study was carried and regulation was still being pursued. In addition Sprung (2016), similarly with data from 2015 found little evidence of this focus on the WPE. 'Reasons' for choice of *C. longa* preparation did not include the WPE focus. The 'natural' WPE may therefore have recently increased in importance.

Evidence for the effect of regulatory 'pressure' also comes from other countries where WHM is practiced and where this 'modernising' drive continues, specifically Australia, Canada and New Zealand (Ng, 2020; Ooi et al., 2018; Cottingham et al., 2015). Greater focus on regulation has been associated with increasing adoption of modern scientific evidence and research-based products (Niemeyer et al., 2013) and therefore less focus on the natural WPE. This is evidenced more recently in Steel et al. (2021) who surveyed international naturopaths. They found widespread reported reliance on research evidence and marketing information from supplement companies, associated with use of proprietary research-based products rather than the natural WPE. The relatively recent development of this engagement with such preparations is evidenced in earlier findings of greater focus on TK in CAM practitioners (Leach & Gillham, 2011) and little influence of marketing information in Braun et al. (2013).

It is proposed that the regulatory drive in the UK may therefore have somewhat reduced the focus on the WPE historically; this is supported by Nissen (2010) finding that regulation was largely viewed favourably in the UK.

The clarity of this focus is supported by further evidence from the survey and contrasts with the lack of strong feelings identified about HSE. Respondents appeared to be clear about their central message; they only occasionally provided other reasons for preferring WPEs. For example there was little overt mention of clinical effectiveness and convenience, that both directly support the crucial positive therapeutic outcome, and were the most important reasons for choice of *C. longa* WPE preparation in Sprung (2016). Comparisons of the surveys are suggested cautiously given lack of standardisation. It is assumed that these factors supporting effective therapy remain important reasons for choice of product. This suggests that herbalists, when completing the survey or discussing the topic, were focusing almost exclusively on central beliefs about the nature of WPEs, assumed to be at the forefront of their minds, rather than more practical issues of treatment outcome. In addition Waddell (2016) comments on the widespread use of 'intuition' or non-logical processes in decision making, as supported by interview and WHMQ data and identified in VanMarie (2002) and Leach & Gillham (2011) more widely in CAM. There were no similar comments in the survey. It seems that this central message about the nature of WPEs was what most herbalists wished to convey about the topic and other important issues were not as pressing.

The limited use of HSE in this study is also considered to reflect the strength of feeling about the natural WPE. Although use was widespread, utilisation was largely only single HSEs (mostly *C. longa*) rather than a wider engagement with (the few) available preparations. The limited focus is further supported in survey data through only a small minority of HSE-users reporting relying solely on HSEs when following HSE research studies. This suggests that these herbs are not always used as the HSE preparation by those users. It is suggested that many find *C. longa* HSE specifically useful as an individual 'unique' product in its own right, utilising its characteristic clinical strength rather than acceptance of the concept of 'HSE' more generally. Factors encouraging use that single it out from other HSEs are the identified strong body of research evidence outlined in Chapter 4, and specific historical promotion of the 'novel' product in herbalist seminars and by supplement companies. This may have afforded it a position rather more separate from others. Evidence for such limited HSE use supports the proposed strength of the WPE focus.

7.2.2 The central focus on the WPE as related to underlying philosophy of practice: Evidence from other communities

Having suggested a renewed strong focus on the natural WPE, with recently reduced 'modernising' regulatory pressure, evidence is sought to explain this further. The theory that this is encouraged by a relatively unspecified and diverse philosophical basis is supported more

widely through other herbal traditions that conversely have a more 'fixed' philosophy, as well as similar suggestions from conventional medicine. This is discussed below.

In addition to being understood as historically linked to TK, the centrality of the natural WPE may also be understood as being a focus on what is best 'known' in WHM, the herbs themselves (Waddell, 2016). This contrasts with the wider WHM philosophy that is not respected in the modern world (Wahlberg, 2010) and which is relatively 'diverse' compared to other herbal traditions (Waddell, 2016) and other CAM modalities. A focus on the WPE herbs that may be more 'relatable' therefore encourages recognition in the wider world. This was discussed in Chapter 1, with WHM being associated with a '*plurality of practices*' (Nissen, 2011, p. 166), and a '*mass of tensions*' (Waddell, 2016, p. 1) that may '*almost def(y) definition*' (Jackson-Main, 2005, p. 89). Diversity of WHM philosophy is partly associated with those changes in the final decades of the 20th Century when European scientific approaches were introduced to herbalist training, largely replacing the 'vitalistic' American Physiomedical tradition which had been influential previously (Barker, 2007; Waddell, 2016). This uniformity in WPE focus therefore offers some important definition for WHM, despite Waddell's (2016) finding of diverse paths into the WHM profession. Backgrounds were identified as traditional or science-based and this was also found in interviews here, but without any indication of them determining attitudes towards WPE or HSE.

Evidence for this theory that WHM philosophy encourages a focus on the herbs is found in the current study through reported general engagement with research studies compared to the limited acceptance of 'changed' HSE herbs. In contrast to WHM, the methods of other traditions, such as Traditional Chinese Medicine (TCM) and Ayurveda, are less readily modified than the herbs, although data is limited. Considering the herbs first, there is widespread acceptance of research-based standardised TCM herbal formulae in the form of tablets and capsules in contrast to non-standardised individualised prescriptions in the form of decoctions (aqueous extracts of dried herbs) (Tang et al., 2008). This suggests that TCM practitioners may be more open than those in WHM to their herbal preparations being 'altered' by research findings and processing. This may support the more central place for the herbs in WHM compared to TCM.

In addition, the methods of TCM, with more explicitly presented concepts, may not be readily modified. There is no evidence of widespread acceptance of modern research studies by practitioners of other herbal traditions as has been found here. As in WHM, there have been decades-long drives to integrate the research-based EBM approach and TCM in China (Tian et al., 2021). Indeed Western medicine is included in TCM training and the two practices are commonly used alongside each other (Tang et al., 2008; Wang et al., 2017; Zhang & Tang,

2020; Wang & Zhang, 2017; Chen & Xu, 2003). Modern research in TCM has been growing for over 20 years, similar to WHM, and has been influential on clinical guidelines and herbal preparations (Tang et al., 2008; Tian et al., 2021) although continuing efforts are made to develop practice-appropriate research methods (Tian et al., 2021; Fung & Linn, 2015; Tang, 2006; Tang et al., 2008) as also reflected in WHM. Despite this much closer relationship between TCM and conventional research-based healthcare in China compared to WHM in the West, evidence suggests only moderate 'open-mindedness' to modern research amongst TCM practitioners in Hong Kong (Lam & Sun, 2013). Complex underlying philosophies in TCM are generally viewed as relatively incompatible with modern science methods and practitioners were concerned about integration of Western healthcare models and training on their practice. This limited engagement of TCM practitioners with modern research despite the long and close history of TCM and the EBM approach in China offers evidence of the resistance to change of the central methods, and despite apparent achievements to 'modernise' TCM, as reflected in high levels of 'professionalism' found in TCM practitioners (Kwan et al., 2020). Given the close relationship between Western conventional medicine and TCM in China it is notable that there has not been more reported acceptance of research evidence by TCM practitioners, supporting the theory the methods are resistant to engagement with other philosophies. Furthermore, in Scotland, Spence (2013) found TCM practitioners had a lack of engagement with or understanding of research methods, offering further evidence for resistance of TCM philosophies to change. There is less data concerning integration of research-based evidence in Ayurveda, although there have also been calls for integration of science and tradition to modernise the profession (Patwardhan, 2013; Chaturvedi et al., 2021), with specific concerns about loss of professionalism (Dornala & Dornala, 2020; Rathi & Rathi, 2019). It is not clear how practitioners are engaging with this, however, there appears to be a barrier towards scientific methods (Chaturvedi et al., 2021) and moves to integrate with conventional healthcare have been limited at least partly due to philosophical differences (Shrivastava et al., 2015).

In conventional medicine it may be suggested that the central focus on medication leads to the relative 'over-prescription' (Mir et al., 2021) over a wide range of commonly used drug classes (Alduhishy, 2018; Watkins & Bonomo, 2020; Fletcher-Lartey et al., 2016; Savarino et al., 2018) with evidence of inconsistent use of EBM methods and guidelines (Wang & Groene, 2020; Cunningham et al., 2019; Mascia et al., 2013;2014; Mascia & Cicchetti, 2011; Scurlock-Evans et al., 2015). This may, similarly to UK WHM, suggest a stronger focus on the medicines in the relative absence of a strong underlying philosophy of practice.

7.3 Limited 'integration' of research-based evidence in the responding population

A strong central focus on the 'natural' WPE has been found, that is proposed to limit HSE use, but 'allows' engagement with modern research studies that do not challenge the WPE. These findings are now taken into the wider debate concerning the 'integration' of research-based evidence and practice based on TK. 'Integration' is understood here to refer to the clinically informative use of research-based evidence in WHM practice that largely relies on TK. The discussion below attempts to understand this idea of integration further.

In addition to relative uniformity of the WPE focus discussed above, all survey participants reported utilising a wide range of herbal studies, another uniformity in a profession that is considered diverse. The section below offers a proposal for how this engagement across the entire responding population has happened and how the research is used. Comparisons are made between HSE users, non-users and herbalists outside the UK. Little evidence is identified of influence from a long history of research methods training or the regulatory drive, but rather encouragement from the increasing herbal research base (section 7.3.1). This acceptance of research is identified as two types. The first type is considered 'integrated' use where studies are reportedly used to support limited prescription of HSEs by the responding minority in a practice based on WPE. The second type is use of research for non-clinical reasons, reported for interest and communication in the 'modern' scientific world. This is associated with WPE use which does not 'need' research evidence, being based on TK (sections 7.3.2 and 7.3.3). This type of research use is not considered to be 'integrated' with WHM practice. There is also some suggestion of 'inappropriate' use of HSE research and variable research-literacy (section 7.3.4). A contrast is seen with WHM outside the UK where research and TK 'integration' is identified as more 'overt'. This is associated with greater external pressures to engage with research evidence and reliance on research-based proprietary products. Although greater integration in other countries is seen as possible without research evidence 'taking over' it is associated with population divisions and variable focus on the natural WPE. This contrasts with the relative uniformity and WPE focus in respondents here (section 7.3.5). These issues are discussed below.

7.3.1 How UK herbalists have come to engage with research: The changing body rather than training in research methods.

All participants in the survey reported use of a wide range of herbal studies. There were no differences in reported frequency of use between the HSE users and non-users. Research was the strongest reported influence on the limited use of HSE. This contrasts with previous evidence that suggested reduced reported engagement with research studies in the UK (Nissen, 2015; VanMarie, 2002; Sprung, 2016). It has also been limited compared to other

WHM countries, as discussed in Chapter 2, although generally has been seen as possible (Waddell, 2016). Findings here therefore suggest a change in attitudes. This is proposed to be largely due to the recently increased body of herbal RCTs, rather than the overt effect of the long history of training in research methods. Training appears to have led to little increase in research use compared to other countries where regulatory pressures have been greater. The greater reported acceptance in this study of historically controversial modern research compared to little HSE use is proposed to be due to the lack of 'challenge' that research methods pose to the central focus of WPE use.

The large majority of responding herbalists reported being trained in research analysis, HSE users being more likely to report training than non-HSE users. It might be proposed that this training is important in the adoption of research. Conway (2005) suggested that it would lead to 'integration' of research-based evidence and TK, and therefore reduced controversy. Steel & Adams (2011) identified a lack of such skills in Australian naturopaths inhibiting research use and Leach and Gillham (2011) also suggested that support and training would facilitate clinical use in widely engaged Australian CAM professionals. The focus on supporting research use with training continues (Steel et al., 2019). Leach & Tucker (2017) discussed the 'research-practice gap' in CAM therapies and concluded that this gap would close with research literacy, however this is also an issue in conventional healthcare (Hickman et al., 2018). This overt influence of such a focus on research is reflected in quicker adoption outside the UK, but there has been little evidence of this happening as a result of a history of training in the UK (Sprung, 2016; Waddell, 2016; Nissen, 2015). This proposed relative lack of influence of training on use of research is also reflected in the wider healthcare arena where there have also long been questions about EBM methods (outlined in Chapter 2). Cunningham et al. (2019) found doctors, with a strong focus on research methods in their training, reported 'disproportionate' influence from other healthcare professionals and clinical practice compared to research-based evidence, and other studies suggested inconsistent use of research and guidelines (Wang & Groene, 2020; Mascia et al., 2013;2014; Mascia & Cicchetti, 2011; Scurlock-Evans et al., 2015). This may relate to time pressure (Andrews et al., 2005) but this is not reported as an issue in WHM largely due to part-time work (Steel & Adams, 2011a; Cottingham et al., 2015; Nissen, 2010).

The reported more rapid adoption of research evidence in Australia compared to the UK may relate to the greater pressure from the ongoing drive for regulation and state support for modernising the profession (Ooi et al., 2018) as well as widespread preference for regulation (Braun et al., 2013; Ooi et al., 2018). Research suggests that 'attitudes' towards EBM (Zhang et al., 2022) and organisational culture (Li et al., 2018b) are crucial for implementation of the

methods. Training alone is found insufficient for engagement (Rycroft-Malone et al., 2004; Hickman et al., 2018). Training in research methods in UK WHM has not historically been associated with such strong professional or governmental support, although the moves towards regulation were widely accepted (Nissen, 2010).

There is therefore limited evidence in the UK of an increased focus on research evidence increasing research engagement, proposed as related to lack of overt professional pressure. Widespread reported training found in this study is therefore not suggested as a central reason for the overwhelming reported use of research. The minority group of non-research-trained herbalists in the survey also reported engagement as much as others, further supporting this theory of lack of influence from training. The significant change identified here that may have facilitated overwhelming acceptance is rather associated with a reported focus on a wide range of herbal RCTs, both HSE and WPE studies. This body has recently grown rapidly, particularly WPE RCTs, adding to the relatively more controversial HSE and/or preclinical studies. The previously existing evidence base may therefore have limited the engagement of herbalists despite research methods training being associated in this study with HSE use and associated open-mindedness and reduced controversy. Supporting this theory, Steel & Adams (2011a) suggested the strong naturopathic focus on research in other countries was also related to the rapidly increasing research base. This increase in studies, including RCTs, is represented in timeline charts from PubMed searches (Appendix 1-2; Table 3.1), including a range of WPE herbs to rival that for HSE herbs. This body of evidence may offer an explanation for how reported overt engagement has happened only recently, having previously been viewed as 'possible' (Waddell, 2016). The strong reported influence of research on HSE use from HSE users in the survey suggests that they are using the recently increased body of HSE research for informing HSE use. In contrast, non-HSE users who reported using a wide range of WPE studies are largely using the recently increased body of WPE studies.

As suggested in section 7.2, the strong focus on the natural WPE may be less readily changed than the methods of WHM which offers further explanation for how research has become so accepted. Historically controversial research methods that largely do not reflect WHM practice may be readily adopted as they do not challenge the strong central focus on the natural WPE. There was no evidence of remaining controversy or general 'objections' to modern research methods identified in the study. This contrasts with limited HSE use that is still somewhat controversial.

7.3.2 Some limited evidence of 'integration' of research-based evidence in HSE users but not non-HSE users

Herbalists have been described above as accepting the increasing research body, with comparatively little regulatory pressure influencing use. The discussion further considers the nature of this use which may appear at first sight to represent 'integration' of research-based evidence and TK, as suggested by Waddell (2016) and Wahlberg (2008). 'Integration' is understood here to mean that research evidence as well as TK is used to inform practice. Considering reported use of research studies in data here, evidence of 'meaningful' integration is limited to reported use of HSE research to support HSE prescription. In contrast, use of research by non-HSE users is not reported as influencing practice, rather being for reasons of interest and associated engagement in the wider community. This is not considered here to represent meaningful integration and is discussed below.

A small element of research-based evidence 'integration' was identified in the survey with HSE users' strong reported reliance on research to inform use of individual HSEs. This mostly relates to the very large compelling body of evidence for *C. longa* HSE. Greater integration is found in the small minority of herbalists in the current study, and HSE-using interviewees, who were more 'positive' about HSE. Amongst this minority is likely to be those more experienced herbalists who were reported by other practitioners to be influential in use of HSE.

Other evidence of 'strong' influences on HSE use (recommendation from other herbalists and clinical evidence from practice) are not considered to detract from the claims that research evidence is relied on. It is proposed that HSE users were historically influenced by other experienced herbalists and herbalist seminars (less so supplement company seminars) and the large body of research, which has led to positive findings in clinical practice. All these influences are considered to be possible for an individual HSE user. These factors of influence from other herbalists and evidence from practice are to be expected. They are the only identified factors that persisted between the author's previous study and this one, suggesting that these are central enduring characteristics of WHM. The identified importance of other herbalists reflects Treasure's (2014) concept of 'Eminence-based medicine'. He proposed that knowledge from traditional 'Herbals', authored by 'eminent' experienced herbalists was replaced in the drive to modernise WHM, by the scientific 'monograph'. Findings here suggest that this endures but may be less strong an influence than research evidence in other WHM populations that rely on research-based products. The importance of research evidence is stated as similarly (Braun et al., 2013) if not more so important (Steel et al., 2021; Steel & Adams, 2011a; Leach & Gillham, 2011) than the influence of other practitioners or evidence from practice. It has been suggested that limited contact with colleagues in naturopathy

compared to conventional healthcare is related to that relatively reduced influence (Steel & Adams, 2011a) and this is similar in the UK (Nissen, 2010). For whatever reason, the influence of research appears stronger than these other factors. This supports the theory that HSE users here are relying strongly on research evidence to support HSE use, as reflected in these other countries where research-based products are more widely used.

Further suggestions for this overt influence of research evidence for HSE users comes from suggestions that that there was little effect of herbal texts on HSE use, including that identified by Waddell (2016) as the 'authoritative' textbook in WHM (Mills and Bone 2000; Bone and Mills, 2013). Herbal texts may offer summaries of research evidence, and reported use of research by HSE users may imply that they use texts rather than original research studies directly. However, there is no evidence that this is the case from interviews or survey. Indeed relative reported use of individual HSEs even appear negatively correlated with text recommendations (Table 3.2, p. 36). The most frequently used *C. longa* HSE is recommended largely as small doses of the WPE in texts whereas HSE preparations are more widely recommended for the other HSE herbs considered here, but with far less reported HSE use. As mentioned earlier, conclusions are limited by no data on how widely used these herbs are in general. Highest reported use of *C. longa* may reflect use by the large majority of herbalists as found in Sprung (2016). Entries in a large number of identified herbal texts for the other HSE herbs does suggest widespread use for these as well, although this cannot be confirmed at this point, particularly with questions concerning the use of texts.

This suggested lack of influence of herbal texts contrasts with greater reported use in more general CAM practice. Steel et al.'s (2021) study of international naturopaths found that the majority relied on modern texts at least sometimes and a majority also similarly reported use of clinical guidelines; this was also found in Steel & Adams (2011a) and in addition CAM professionals were also found to rely on both (Leach & Gillham, 2011). It is not clear whether a lack of use in the current study relates only to HSE or for wider information. Since texts have been found to be influential in a wider WHM context it may be that they are more useful for non-HSE herbs, as indicated by interviewee No.2. A suggestion that they are not influential in HSE use further supports the reports of the strong influence of research studies.

This likely strong reliance on research in an 'integrated' way by HSE users, to directly inform HSE use, contrasts with the majority group of non-HSE users. This group are not understood to use research to inform their clinical practice that uses WPE herbs only. Data suggests that research use by non-HSE users is for non-clinical reasons, that rather allows engagement with the wider world. There is little evidence of Conway's (2005) prediction that training in research

methods would lead to integration of research-based evidence with TK; research studies have become accepted for other purposes.

Interview and survey data offered evidence for how research is used by non-HSE users, and this contrasts with HSE users. Interview data offered only 'negative' comments concerning research from non-HSE users. In the survey there was only one comment of many suggesting an influence in prescribing compared to many more that indicated other non-clinical reasons. These were stated as use for general interest, for passing on to patients, herbal talks and support for traditional use. These stated reasons of research use for non-clinical reasons reflect the aim of promoting WHM professionalisation and having a common language for engaging with the modern world where conventional healthcare claims to be EBM-based. This has been a focus of the long history of modernisation of the profession (discussed in Chapter 2) with a lack of 'value' placed on TK outside WHM (Wahlberg, 2010). Engagement with this process is suggested by Nissen (2010) who found that UK NIMH herbalists preferred the title 'medical herbalist' over 'herbalist' which may promote a more modern professional image.

The use of research for non-clinical reasons that rather promotes a 'modern' image is reflected in Wahlberg's (2010) discussion of 'normalization' of WHM within a scientific framework. Identification of 'active' constituents and the development of 'plausibility' through scientific mechanisms of action were proposed as central to this process. However, although Waddell (2016) and Wahlberg (2008) both discuss the role that the concept of 'synergy' of constituents plays in finding common ground between TK and research-based evidence, they acknowledge that otherwise there is little acknowledgement in the modern scientific approach of other central characteristics of traditional WHM. These processes therefore suggest how WHM may become 'plausible' in the modern scientific world but not how research evidence would be meaningfully integrated with TK by practitioners. Herbalists here appear to have engaged with this 'normalization' but without practical integration. With comparatively less pressure in the UK to adapt, the profession may have found its own way of uniformly 'modernising', using non-integrated engagement with research evidence to increase 'plausibility' in the wider healthcare arena. Reported use of most research is therefore not considered to represent 'overt' integration. Although Waddell (2016) suggested that UK herbalists considered integration possible there is little evidence of this to date, apart from that identified in HSE users.

This 'professionalisation', yet retaining clinical autonomy was found in a study of herbal practitioners in Australia (Wiese and Oster, 2010) and suggested by Snow (2016). Lack of overt influence of research studies was also found in VanMarie (2002) despite evidence of some engagement with research amongst UK herbalists. That is not to say that research evidence

may never be used in a clinically informative way, but that it is not how participants generally reported it here.

Conway's (2005) proposal that herbalists' concerns about research taking over would lessen with research training appears to have come to pass, albeit proposed to be largely related to the growing WPE evidence base rather than training. There is no suggestion that respondents are 'concerned' about the impact of engagement with research on WHM practice that focuses on WPEs rather than philosophical methods. However, there is only limited evidence of predictions that this engagement would lead to meaningful integration of research-based evidence and a practice based on TK.

Finally, considering this use of research for purposes of engagement in the modern world and with conventional healthcare, it has already been noted in Chapter 2 that typical EBM methods relying on RCT evidence have a long history of being questioned, as they detract from patient-centred care and expert experience (Greenalgh, 2020; Fernandez et al., 2015; Miles & Loughlin, 2006; Cohn & Hersh, 2004; Sur & Dahm, 2011). The clinical influence of research evidence has been found to be limited (Cunningham et al., 2019). The most important factor in both arenas of WHM and conventional healthcare may therefore be the shared language of research itself rather than actual everyday practical application of evidence.

7.3.3 Suggestion for why there is little evidence of research 'integration' in the responding population: lack of 'need'.

A lack of evidence for 'integration' of research-based evidence and TK in non-HSE users suggests that there is little clinical use for research evidence in informing WPE use. Although the research base largely does not reflect WPE preparations used by herbalists this is not considered to be the major reason for not relying on it for informing clinical decisions. There is no evidence that herbalists are 'opposed' to research evidence generally. The proposed reason is that it is not 'needed' for informing WPE use that rather relies on TK. In contrast, greater evidence of integration is found in HSE users and in non-UK countries where there is stronger reliance on research-based products. The use of such preparations, which include HSE, is supported by research-based evidence rather than TK and therefore research is 'needed' for informing use. This is now considered.

It might be suggested that the reason for little identified integration of research-based evidence and WHM practice is related to the evidence base that largely does not reflect doses or preparations used in UK WHM; they are relatively unprocessed and unspecified (as discussed in Chapter 1). However the evidence is mixed and there are studies that better reflect TK. For example, a survey of PubMed for herbal WPE RCTs found that most RCTs on *M. Recucita* (chamomile) involved extracts that do not reflect the natural WPE but the large

majority of studies on *Z. officinale* (ginger) largely used the WPE whole unprocessed powder at similar gram-doses that might be used by UK herbalists. The comments made about research in the survey offered no suggestion here that the research base is considered unsuitable for informing practice. It is rather proposed that the evidence base is simply not 'needed' for prescription of most natural WPEs¹⁵ that have a basis for use in TK. This contrasts with other countries where there is a greater integration of research-based evidence and TK (Ooi et al., 2018; Aucoin et al., 2021; Cottingham et al., 2015), with evidence of research being the most important reported influence on clinical decision-making (Steel et al., 2021). There is a greater reliance on research-based products in these countries, as reflected in strong reliance on related manufacturer information (Steel et al., 2021; Smith et al., 2005; Steel & Adams, 2011a;b). As discussed earlier, there have been concerns outside the UK about such increasing use (Niemeyer et al., 2013). The evidence base is therefore more necessary and informative for clinical use of these preparations and reflects the 'need' to keep up with the rapidly increasing literature in Steel & Adams (2011a). Similarly in the current study, a reported strong reliance on research to support the limited use of HSEs reflects practice in other countries. This is particularly noted in the small minority of more 'positive' herbalists and those HSE users in interviews who reported greater HSE and research use and associated with no comments about the WPE.

7.3.4 Questions concerning use of research: Is it 'inappropriate', lacking research-literacy, with herbalists being 'easily influenced'?

The use of HSE research to inform the limited use of HSE has been identified in HSE users here and is considered to represent 'meaningful' integration of research-based evidence and TK. There is also evidence of HSE research being used to inform WPE use by HSE users and even more frequently in non-HSE users. This is considered possibly 'inappropriate' use of HSE research (Evans, 2008) and may suggest poor research-literacy. Evidence for limited research-literacy is greater in non-HSE users but may be less significant than initially appears due to it largely relating the 'unique' *C. longa*. It is also suggested that 'open-mindedness' towards HSE does not suggest being 'easily influenced'. These issues are discussed below.

All non-HSE users and some HSE-users reported use of the WPE herb following use of HSE research, which may suggest variable research-literacy. Further evidence of relatively greater research-literacy of HSE users is found in the association of HSE users with research methods training and membership of the CPP which has a central focus on research (CPP, 2021). This limitation may be expected as it is also an issue in populations where there is greater

¹⁵ There may be exceptions such as modern the use recorded in herbal texts of *U. dioica* root (nettle) in benign prostatic hypertrophy which is based on research evidence.

integration of research and TK (Cottingham et al., 2015). It is assumed that reasons for the association between training courses or PAs with a research focus, and HSE use, are due to that focus on research-literacy rather than overt recommendation of HSE. The author and supervisor are not aware of any recommendation of HSE in any training schools of which they have had experience, the author as a student, and supervisor as lead clinical supervisor and lecturer. The author, who trained at the University of East London, recalls being trained to use only *S. marianum* preparations that efficiently extracted silymarin, following research carried out at the university that found silymarin content related to strength of alcohol solvent. However this is not considered to constitute overt recommendation of the HSE, but rather attention to the benefits of integrating research evidence (Pendry, Busia & Bell, 2006; Pendry et al, 2017).

There is evidence of possible 'inappropriate' recommendations in herbal texts. Waddell's (2016) identified central 'WHM text' (Mills & Bone, 2013; 2003) that includes a research focus, recommends *C. longa* WPE. It may be viewed as supporting this possible 'inappropriate' use. However, since most identified 'inappropriate' use in this study also relates to *C. longa*, this 'unique' herb (see 7.2.1) may be viewed differently to others. Sprung (2016) found that 92% of nearly half of NIMH herbalists reported use of it in clinical practice. The issue of 'inappropriate' use of research and suggestions of variable research literacy may therefore be limited but may also suggest how compelling bodies of evidence for herbs can encourage this practice.

Following on from possible 'inappropriate' use of HSE research, there was widespread 'open-mindedness' towards HSE identified in the survey. Another way of looking at this is being 'easily influenced'. This is suggested following the very high use of the novel *C. longa* HSE in the author's previous study, proposed as following supplement company and herbalist promotion of this novel product; this also identified as a more minor factor in the current study. Other evidence of such ready adoption of novel preparations is the use of recently developed 'CBD' oil products. A search of WHMQ archive (that was closed by 2021) found 393 results for 'CBD' from 2015 onwards, compared to only 156 comments for 'curcumin', suggesting a wide interest in these novel CBD products. Although the pattern of CBD product use over time is not obvious, the promotion of CBD products by manufacturers at herbalists' conferences such as the NIMH, does have similarities with the historical promotion of *C. longa* HSE.

As mentioned above, outside the UK the large majority of naturopaths surveyed have reported manufacturer information useful (Steel et al., 2021; Smith et al., 2005; Steel & Adams, 2011a;b) but it is also considered not 'trustworthy' (Smith et al., 2005; Steel & Adams, 2011a), and use was associated with 'wariness' (Steel & Adams, 2011b). This attitude was also

reflected in survey comments in the current study. Such attitudes may suggest that practitioners are careful to avoid being 'easily influenced' by this relatively recent way of obtaining information. Earlier findings suggested little engagement (Braun et al., 2013), suggesting more recent reliance on this source. Although a lack of 'wariness' in conventional healthcare towards influential marketing (Larkin et al., 2021; Gill et al., 1996; McGettigan et al., 2001) has led to calls for awareness of this issue (Larkin et al., 2021) so herbalists should continue to be 'wary' as is suggested to be the case above.

Being 'easily-influenced' is also not suggested by the identified enduring commitment to WPE and the association of open-mindedness to HSE with research methods training. In addition there is also no evidence that choice of herbal preparation is based on mis-placed reasons. For example few reported comments about HSE safety from non-HSE users suggests that herbalists do not have un-warranted concerns. Research suggests HSEs are very safe (Ahmad et al., 2020; Soleimani et al., 2019; Diamond & Bailey, 2013; Lao et al., 2006; Sharma et al., 2004; Novara et al., 2016), particularly when compared to wider herbal safety (Bensoussan et al., 2004; Lin et al., 2009). 'Open-mindedness' therefore may not reflect herbalists being 'easily influenced', but rather open to new additions within the context of the focus on the natural WPE.

7.3.5 A closer look at 'integration' of research-based evidence

The limited signs of integration of research-based evidence and TK in HSE users here are reflected in a larger sense in ongoing increasing integration in non-UK countries, with greater use of research-based products. Rather than a 'take-over' by the research-based EBM philosophy being necessary, both may have a place in practice. This may also be associated with remaining divisions within populations and such integration remains a challenge. A contrast is drawn with the population in the current study that shows little sign of either meaningful integration of philosophies or division within the population. It is also not clear if commitment to both philosophies is possible; this is discussed below.

Findings concerning the strong influence of research evidence in non-UK populations contrast with earlier findings in Australian CAM practitioners that suggested a greater reliance on traditional knowledge and herbal texts (Leach & Gilham, 2011). As discussed in Chapter 2, this ongoing process of increased research reliance was feared to lead to a relative 'scientificization' (Wahlberg, 2008) or 'colonization' (Waddell, 2008) of WHM. The less firmly rooted WHM philosophy might be more easily over-ridden (Barry, 2006) with use of associated research-based preparations. This represents a paradigm shift as predicted by Niemeyer et al. (2013) and Treasure (2014). With fears of the scientific approach 'taking-over' (Niemeyer et al., 2013; Braun et al., 2013; Evans, 2008;2009; Casey, 2009; Singer & Fisher, 2007) the 'challenge'

was to 'normalize' (Wahlberg, 2010) and integrate research-based evidence with TK. This has been seen as possible (Conway, 2005; Waddell, 2016; Wahlberg, 2010) and despite the increasing integration in non-UK countries there is no evidence that it has 'taken-over' WHM. Steel et al. (2021) found reported usefulness of published research and traditional naturopathy texts were reported as similarly and highly useful for informing clinical decision-making for the large majority of participants. This suggests a widespread 'balanced' integration of research-based evidence and TK is possible.

However signs of division remain in such 'integrated' populations, although possibly less so than in the past. It is not clear whether this will continue to become less overt and lead to a WHM population where all practice in an 'integrated' way. Integration of research-based evidence and TK remains a challenge and the debate is ongoing, particularly in naturopathy literature outside the UK (Steel et al., 2019). In Steel et al. (2021) above, ¼ of naturopaths reported no use of modern research. This reflects the previously identified central split in Australia between 'science-orientated' and 'traditional' practitioners (Singer & Fisher, 2007). The split may have been due to the relatively high pressure to adopt scientific methods and research-based products (Ooi et al., 2018), leading to 'rebellion' and division. Regulatory control may limit the relative autonomy with which these changes happen (Steuter, 2002; Wiese & Oster, 2010). Although regulation is not established in Australia similar existing pressures may have a similar effect of somewhat 'forcing' change. In UK findings here, with less overt pressure, there is no such identified central division between 'science' and 'tradition' in the current study, but there were identified opposing views when regulation was being sought (VanMarie, 2002). Findings of uniformity in the responding UK population here suggests that a central focus on WPE and TK can exist alongside acceptance of research as it does not challenge WPE use. Conversely, the use of research-based HSEs does challenge the WPE focus and therefore may lead to division.

Finally, the question of Treasure's (2014) 'incommensurability' of research-based evidence and TK is addressed. Central findings in the current study rather suggest that a strong WPE focus is relatively 'incommensurable' with HSEs, but not with universally accepted modern research methods. These associated issues of modern research and HSE are therefore considered separated. In theory, acceptance of published research in this study suggests that research-based evidence and TK would be more 'integrated' if there was a 'need' for such research evidence to inform WPEs. Although this is possible, the lack of need may hinder it. This 'possibility' reflects the proposed 'modifiability' of the diverse WHM philosophy, discussed in 7.2.2. It suggests that in theory there are no overt barriers to integration of research-based evidence and TK despite the evidence base not reflecting WHM practice. Modern research

methods no longer appear at all controversial, unlike HSEs which are accepted in only a limited way as they challenge the WPE. Despite herbalists being accepting of modern research methods they may however continue to be used largely for non-clinical reasons. It may not matter whether the evidence base is 'inappropriate' for informing use of the WPE as it does not reflect practice (Niemeyer et al., 2013) or there is no 'need' for it, the outcomes may be the same.

Meaningful integration of research informing WPE use therefore may be seen as 'theoretically possible' as also reported by Waddell (2016) but there is little evidence of this happening. Steel et al. (2021) rather found only the side-by-side use of research-informed herbal products such as HSE and TK-informed WPE, as also identified in the current study. However it is not clear how these approaches integrate more philosophically or whether it is possible to 'commit' fully to both. Although Singer and Fisher (2007) suggested that integrating seemingly opposing philosophies was a skill of herbalists, there may rather be a reduced focus or 'commitment' to both. This is shown in the strong central focus on the natural WPE here being proposed to limit HSE use. There is no evidence of a population that both fully engages with research evidence to inform research-based products and that also strongly focuses on the natural WPE. This may better reflect the 'incommensurability' of the philosophies as proposed by Treasure (2014). There is a lack of evidence to further inform this question, reflecting Steel et al.'s (2021) call for more research.

7.4 Picture of the responding population: Strong WPE focus limits HSE use and integration of research-based evidence but allows non-integrated research engagement.

A picture of the responding population is offered with a strong central focus on the WPE and widespread 'integration' of specific HSE research, in a TK-based practice, to largely inform use of a single HSE. This identified 'integration' is proposed to be limited by the WPE focus that limits 'challenging' HSE use. The majority of the population appears engaged with research for non-clinical reasons of facilitating communication in the wider world; WPE use based on TK may have little 'need' for clinically-informative research evidence and there is no evidence identified of 'meaningful' integration here. A small minority who are more 'positive' about HSE may better represent practice in other countries where engagement with the modern scientific research occurs in a more 'integrated' way. However this approach is associated with greater divisions within populations and more variable focus on TK and the natural WPE. Both approaches to research - in this study and outside the UK - may offer 'modernising' engagement with the wider world. It may also be suggested that the proposed increased focus on the natural WPE and relative lack of meaningful research integration indicates a move back

towards a 'pre-modern' philosophy. This was suggested necessary for WHM survival by Treasure (2014), in contrast to pursuing integration with research-based evidence. These moves may be supported by the end of the drive towards regulation reducing the likelihood of increased impetus to integrate and adopt research-supported preparations. However, how universal reported engagement with research fits here is not clear. Although it is largely not considered 'integrated' use there nevertheless remains a strong reported focus on research studies. There is little evidence of objection to typical research methods that do not reflect WHM practice or of more general issues concerning research evidence in the wider healthcare arena. Indeed lack of evidence of remaining historical objection to research methods contrasts with ongoing questions about EBM methods in conventional healthcare, as discussed in section 2.1. It is not clear whether herbalists are aware of objections to reliance on positivist RCT evidence that may also be subject to wider, more political influences (Goldenberg, 2006). How this positive engagement with research will develop in the future is unknown. Appendix 17 offers a summary of findings from the results and discussion, showing how HSE use and research use are influenced by a range of factors.

7.5 Discussion of survey methodology and methods: Strengths, weaknesses and proposed improvements

In considering strengths, weaknesses and proposed improvements of the study, first of all the suitability of the methodology and methods is discussed, followed by the limited response rate to interview and survey, and how representative, valid and reliable survey data is. This is followed by suggestions for further research and implications for practice.

7.5.1 Suitability of the methodology

The methods, as described in Chapter 5, were considered to be well suited to the study. It was important in the interview stage that the GT methodology allowed for seeking out a suitable range of participants in order to obtain a wide range of data to inform theory development. If the selection of participants for interview had been randomly selected it is possible that none would have used HSE since no HSE users replied to the initial request for participants and there may have been insufficient clinical experience represented if herbalists with busy practices were not adequately represented.

Theoretical sensitivity was crucial for collection and/or analysis of interview and survey data, for example where responses involved herbs that were not considered to satisfy the definition for HSE in this study and in the many different ways that were used to describe practice.

Without theoretical sensitivity, survey data would have risked been misinterpreted, although the author was aware that what enabled this theoretical sensitivity also risked bias in interpretation. This was a balance that the author was very careful to address, and memoing assisted the author in monitoring the effects of bias. The choice of CGGT was considered to work well in obtaining data as objectively as possible, although recognising the inevitability of influence from the researcher in data collection, analysis and development of theory, particularly given the general knowledge that the author had in advance, concerning the topic of HSE. However this was not considered a reason to abandon the approach which the author believed was the most appropriate for the study. Open interviewing was considered successful; the author had no need to use semi-structured interviews to support data collection if deemed necessary. Interview data was given freely with little intervention. The author believed that open interviewing avoided the risk of more 'standardised' responses from participants that may have emerged from fuller 'conversations'. This is because herbalists are aware of the issue of HSE and it was important to obtain their most strongly held thoughts without encouraging them rather to refer to widely-circulating well-rehearsed general views.

MMR, using qualitative interview and largely quantitative survey methodology was crucial in this study which would probably not have offered such rich theory using either method solely.

Interviews offered basic theory concerning use of HSE and the survey allowed further development to offer a much fuller picture.

7.5.2 Recruitment and response rate

Findings have offered some evidence concerning the difficulties of online recruitment of participants for interview. The number of participants recruited initially was fewer than hoped. Although the author had expected that herbalists would readily offer participation, this was not readily forthcoming. Direct further requests were more successful, as confirmed in the literature (Ryves et al., 2016; Gallo et al., 2014; Barnes & Butler, 2018; Waddell, 2016). Response rate for interview requests may have been improved by using PA affiliation and having the request for participation sent via PAs as it was for the survey link, rather than via Facebook postings which are as yet unproven in their effectiveness (Reagan et al., 2019; Whitaker et al., 2017), particularly for herbalists.

However, looking for reasons for the low response rate may still be useful. Some evidence suggests that it may not have been clear from the online request whether non-HSE users were required to participate, as a response to the online request (Appendix 6) came from an herbalist saying that they did not use HSE and were not sure if their input would be relevant. Additionally an interviewee HSE user also indicated that they were not clear about who was suitable for participation. This was not an issue with direct requests for participation. As an 'insider-researcher', having easy direct personal access to potential participants was an advantage. Costley et al. (2010) found that this gave a good response rate to targeted requests. It also avoided the issue in this study of herbalists thinking that they were not appropriate participants or did not have a valuable opinion.

The response rate of the survey was important for validity of data and reducing bias. The relationship between study methods and response rate was informative for assessing the suitability of the method for obtaining responses and therefore for informing further studies. Since response rates to unsolicited online surveys of health professionals, including those of herbalists, are highly variable (Appendix 10), it is difficult to determine study characteristics for optimising response. An average of 16 % in this study, with up to 19 % from NIMH members was relatively low compared to most other online herbalist studies identified (Table 5.2, p. 70) and it cannot be claimed that responses are representative of the UK population. Response was lower than predicted, particularly given the recent 32% response rate for the 2019 NIMH (2021d) online survey which used similar methods to this current study, although with the benefit of originating from the NIMH directly rather than an individual herbalist. However the response rate was only 18 % in the earlier 2018 NIMH study (NIMH 2021c) which compares favourably with the current study response. It was suggested earlier that the most obvious

variable between these studies was the topic itself. It may therefore be that the low response rate in this study may be related to the relative lack of interest in the study, either compared to NIMH (2021d) or Sprung (2016). The focus of Sprung (2016) was on the herb *C. longa* rather than HSE specifically and it was assumed that HSE, as a similar topic, would be viewed as equally relevant and important. However, the previous focus on an individual herb may have been more universally appealing than the topic of HSE, as *C. longa* was found to be a widely used herb. It is possible that the topic was indeed appealing, as evidenced by survey responses, but communicated poorly. Therefore more emphasis could have been placed on encouraging participation by reducing the emphasis on 'HSE' in the initial information and title and making the topic seem more relevant to wider WHM practice that focuses on WPE. For example the focus could have been reframed as 'Comparing attitudes towards whole plants and HSE in WHM' and this may have been more engaging. Another issue concerning why herbalists may not have been drawn to the topic may be related to confusion about whether participation was required by all practitioners. To address this, wording could therefore have been more explicit. For example, adding a statement that responses from all were suitable, whether they use HSE or not and this may have increased responses.

It is not clear if individually addressed emails from PAs would have increased the response rate (this lack of clarity was noted by Mangione & Van Ness, 2009) but this was not an option that was offered. In addition, it is not known what effect the lengthy introductory information had on the response rate, although this was a necessary inclusion. Since only 30 out of 78 total replies were obtained before repeat postings of the survey link from the PAs and on Facebook pages, this reinforces the importance of reminders in survey response rates (Mangione & Van Ness, 2009 and also found in Sprung, 2016).

Finally, the low response does not support the theory that launching at the time of the first COVID lockdown may have encouraged use of the internet and replying to online messages.

In conclusion, it is likely that this low response rate is to be expected from an online survey for which the topic may not be universally appealing to potential participants or the description may not be appealing, and clarity of participant requirements may have been confusing. This information is informative for future survey research.

7.5.3 Validity issues

There were several questions identified in the survey that challenged validity of the data and this was taken into account in the data analysis; issues concerning specific questions are discussed below.

A central issue was the possibility that participants would answer the questions without understanding the specific nature of the HSEs considered in the study. There was some limited evidence that the definition of HSE in the study was misunderstood, despite care being taken in the introductory information attempting to clarify this required definition (see Appendix 12). This confusion is understandable as the term 'standardised extract' refers to a range of products as discussed earlier and it is not as easy to explain requirements for a survey as it was in interviews. However this was considered limited enough to avoid risking validity of the data, particularly since all HSE users who stated a less highly standardised example in Question 2 also stated a 'correct' HSE as well and therefore their further survey data was considered valid as it was assumed to concern at least the required HSE.

There is potentially a challenge to validity with the wording of Question 2, asking about HSE or HSEs used, where *C. longa* and *S. marianum* were given as examples of typical HSE required for the study, and these were also found to be the most frequently mentioned in responses stating HSE used. It is possible that herbalists may have been influenced to state these examples due to their inclusion in the wording of Question 2, however the author believed that it was necessary to give examples of the defined HSE here to encourage validity of data; since these herbs were the 2 most widely researched plants, they were the most obvious examples. However, given that so few herbalists mentioned *S. marianum* HSE compared to *C. longa* HSE this issue may have had little impact in herbalists' statements of HSE used.

Since survey respondents overwhelmingly indicated a reason for not using HSE as being a focus on the natural aspect of the WPE, this question may have been more informative if it had split the question into the 'major' reason and then 'other' reasons, to encourage more detail about attitudes towards practice. It was not anticipated that this question would elicit such a focused response. In future surveys it may be wise to facilitate wider answers for questions involving such central questions.

Question 12 (Appendix 12, p. 248), concerning which products are used following HSE research, may have been confusing and was not worded well. Seeking information about how 'positive' herbalists are towards use of HSE by asking about whether they follow HSE research by using HSE products, this question had an element of ambiguity and 'assumed' that herbalists used HSE research; it was an awkward question to phrase clearly and there was a risk of confusing participants or obtaining data that was not meaningful. The author could have made it clearer by clarifying that both answers could be chosen rather than having to choose one and that the question referred specifically to following HSE research only. Although the 'other' answer was provided in this case it may have been simpler and clearer to clarify further.

It is possible that responses to Question 14 (Appendix 12, p. 248), concerning comparison of HSE and WPE may have been misunderstood as requiring an explicit 'experiment' in practice as a survey response queried why any herbalist would do this. A re-phrasing of the question may have increased the validity of the responses.

It is possible that since the survey link was distributed more widely on the Facebook platform to increase a low response rate, there are responses from herbalists who are not members of the major PAs considered in this study because the Facebook page 'Western Herbal Medicine Questions' (WHMQ) does not require PA membership and it was not a requirement to complete the question concerning PA membership. As 4 survey responses did not answer the question about PA membership in Question 26 (Appendix 12, p. 250), it is possible that these were not PA members but there was no indication that these responses were not from professional herbalists since WHMQ requires professional training, although not PA membership. Two of these herbalists reported training on the Lincoln University herbal medicine degree course. Survey information also stated that participants should be professional herbalists as a pre-requisite for participation. These valuable few responses are therefore considered to be valid, representative data.

The inclusion of the open text comment box, Question 28, at the end of the survey offered more data than was expected, compared to the author's previous study on a similar topic (Sprung, 2016). It was included for completeness and the author did not expect to find much added value from its inclusion as a similar option in the previous survey had provided so little data. However, the considerable valuable data from provision of that option in this study is a useful finding in itself for informing further research which focuses on the herbal community. It is not clear why the response to this question was so different compared to the previous study. A tentative explanation is that, as discussed above, the strong feeling about the topic from respondents in this current study supported the provision of additional voluntary data, which largely related to WPE use. Although the high response rate to the previous survey may have indicated more universal appeal of the topic possibly due to virtually all herbalists using *C. longa*, it may be that there was not the strength of feeling about it as there was in this case. For future reference, since it may be difficult to predict the strength of feeling about a topic it would seem wise to include an open comments question. In addition the use of this option may also offer insight into how the topic is viewed by herbalists depending on how much data it provides.

The low response rate and the discrepancy in HSE use between this study and the authors previous study of NIMH members suggests that data not be reliable or representative of the herbalist population, although it has been proposed here that some participants may have

suffered from recall bias and forgotten about previous HSE use. Aided recall could have been used in the survey to encourage memory of past HSE use if previous use is indeed under-reported as suggested (Kosicki, 2011), therefore increasing reliability of the data. Evidence however suggests that reduced reported use of HSE in this study is a valid finding as there is a lack of mention of Lamberts Healthcare brand that was 'volunteered' many times in the author's previous study but is mentioned only once in this study. The low response rate also limited the confidence in conclusions suggested by this study as inferential statistics could not be used to support conclusions with findings of significance, although this was not part of the original plan for data analysis. Although there was the perceived risk of an online survey increasing response bias in preventing participation of those who do not engage with 'modern' internet technology is suggested to be minimal, since responses suggested a strong focus on pre-modern TK.

In general validity was supported by internal consistency of survey responses (and lack of conflict between questions when data is analysed). There were differences between interview and survey data that may have been due to the controversial nature of the topic or less thoughtful answers to the anonymous survey (Lelkes et al., 2012) and this may challenge the validity of the data. The author considers that survey answers showed considerable thought and this therefore supports the validity of the survey data and reflects the more 'cautious' nature of interview data.

There is a discrepancy in the data concerning HSE use in the previous survey and the current one which may challenge validity. Limited reported past use of HSE does not account for the findings of reduced use. It is therefore possible that the reduced response rate to this survey compared with the previous one has provided a less representative picture of practice and underestimated the use of HSE curcumin and therefore likely HSE in general. It may also be, however, that some herbalists have forgotten that they used curcumin in the past and the 'previous use' question underestimated past use; this did happen in one of the interviews and No. 2 later remembered that they used to use it at the end of the interview: '*I'd forgotten about using that*'. It is plausible that herbalists may have forgotten about previous use, particularly when filling in a survey quickly and evidence suggests completion of anonymous surveys may be less thoughtful (Lelkes et al, 2012). Although thoughtlessness is not considered to be an issue here with perceived engagement of participants who offered detailed survey answers it is considered that this is an easy thing to forget, particularly since it appears to be an unimportant issue. In addition, high reported use of the Lamberts brand of *C. longa* HSE in the previous study compared to one comment in the current survey also suggests reduced use. The difference in *C. longa* HSE use between the studies is therefore proposed to be due to

reduced use of *C. longa* HSE since the 2015 data rather than under-represented use and the discrepancy in figures is not considered to challenge validity.

Chapter 8: Conclusion

This study provides a wide range and considerable volume of novel valuable data, set out in the results section and discussed above, that has been used to build a theory, according to CGGT methods, about how herbalists have come to use HSE or not and also place the practice of respondents here in a wider context. They offer some insight into wider UK WHM that is so poorly defined, are informative for herbalists, training courses, PAs and the wider interested community and suggest further research. It is acknowledged that conclusions are limited by the response bias.

A summary of findings is presented below, followed by a comment on the research methods. Addressing Aim 3, sharing information in the herbal and wider interested community, implications of the study are then discussed. Finally are suggestions for further research.

8.1 Summary of the findings

This study aimed to investigate how UK herbalists have come to use HSEs following evidence of widespread use of *C. longa* HSE. This issue is important in WHM; it is historically controversial, as it challenges central tenets of traditional practice which focuses on the use of the 'natural' WPE.

A central finding was the very strong focus on the natural WPE. In addition to a long history of traditional use, this may also be understood in relation to the relatively unspecified WHM philosophy (compared to other herbal traditions) which is not valued in the modern world. The WPE focus suggests a central uniformity in the herbalist community, a significant finding in a population that is generally considered diverse. It has persisted despite decades of 'modernising' influences and training that focused on research and professional skills, associated with the historical drive towards regulation. A recently renewed WPE focus since the end of the regulatory drive has been suggested; moves towards regulation have been associated in other countries with increased reliance on research and research-based products such as HSE.

Despite the strong focus on the WPE there was widespread use of HSEs identified here and over half of respondents were considered open to use. Open-mindedness was associated with research methods training in BSc herbal courses and membership of professional associations which focus on research. Such training is proposed to have led to reduced historical controversy concerning modern herbal research methods, with no strong feelings about research-based HSE identified. The WPE focus nevertheless is proposed to limit engagement largely to a single HSE example for individual herbalists. HSEs may therefore be an 'unimportant' part of WHM, used as an 'add-on' that has a limited yet clearly stated place, due

to reported 'strong' characteristics, recommendation from other herbalists and support from the large body of research evidence. The major use of *C. longa*, compared to others, suggests that HSEs in general are not widely used. A focus on this specific 'strong' product, with compelling research evidence and a successful history of promotion by other herbalists (rather than less influential supplement company seminars) has been found useful in its own right.

The strongest reported influence on HSE use was research, but non-HSE users reported accessing research as much as HSE users, another uniformity in the population. The historically controversial issues of HSE and research methods have been previously linked but are now seen separately in this study. This overwhelming stated engagement with modern herbal studies is proposed to be largely due to the recently increased body of herbal RCTs including WPE studies. There was little identified influence from a history of training in research skills that had been predicted to increase engagement. Historically controversial research that still largely does not reflect WHM practice is proposed to be overwhelmingly accepted here. This may be because it does not challenge the important focus on the natural WPE, unlike HSE use. There was no evidence of controversy remaining and may contrast with ongoing controversy concerning EBM methods in conventional healthcare of which herbalists may not be overtly aware. Research use was largely reported for non-clinical reasons, specifically purposes of ongoing 'engagement' in the modern scientific world and for general interest. This is not considered to represent 'integration' with a practice based on TK and WPE, although some evidence is seen in the reported strong influence use of HSE research to inform HSE use. Evidence of such limited integration of research-based evidence and TK in this population informs the current debate about this issue; it is suggested that there is a lack of 'need' for research informing the use of the WPE that is based on TK. In contrast, the clinically informative integration of research seen in HSE users' practice may relate to the 'need' for supporting the use of research-based products such as HSE. Such integration is identified more outside the UK where there is a stronger focus on 'modernisation', professional regulation (Australia, New Zealand, Canada) and use of more research-based herbal products. Signs of divisions between 'science' and 'tradition' associated with this greater integration in other countries contrasts with relative uniformity of reported positive attitudes towards research in this UK study. The small minority of respondents who have been identified as more 'positive' about HSE may better reflect practice in non-UK countries but it is not clear whether full commitment to both HSEs and WPEs is possible. Greater use of HSEs and integration of research evidence in the UK is considered unlikely with no ongoing impetus of the drive for regulation.

This widespread use of research in this study is also associated with signs of 'inappropriate' use of HSE research informing WPE use, and highlighting variable training and research-literacy. However this largely concerns the use of *C. longa* which, identified as a historically widely promoted, useful 'unique' herb may suggest that it is viewed differently to other herbs, although this suggests how 'inappropriate' use may happen.

Finally, a tentative picture is offered from respondents here of UK practice firmly based on a renewed commitment to the natural WPE, yet with 'open-mindedness' to use of a single valued HSE, following a history of training in research methods. Engagement with the apparently non-controversial increasing body of herbal research is useful for interest and communication in the modern world, but is largely not 'needed' for informing practice apart from limited HSE use. How this engagement with research in WHM practice will develop in the future is not clear, particularly given ongoing controversy in wider healthcare.

8.2 Comment on the methods

Although the response rate to the survey was low it is considered to be in the range expected for such an unsolicited online survey for an individual's research study with PA and university affiliation, the topic of which may not be universally relevant and suggestions have been made for improving the response rate. Data is considered of high validity and coherence and the CCGT approach with MMR supported the development of the theory discussed here.

8.3 Implications of study findings in WHM and the wider interested community (Aim 3)

This study offers a range of information for WHM practitioners and the wider interested community about UK herbal practice and the debate concerning HSE and integration of research-based evidence with TK. It is proposed that promotion directly to herbalists will be via channels such as PA conferences and newsletters and future publication in the more widely distributed format of the peer-reviewed journal. This will also add academic weight the study for a wider audience. A discussion of implications of the study below considers the issue of how to offer support for choice of preparation, how engagement with research and the focus on the WPE may be supported, and finally how findings may support engagement with the wider interested community, including conventional healthcare.

8.3.1 Support for choices: sharing widespread evidence from 'everyday' clinical practice

Considering provision of support for choice of preparation, high levels of reported clarity in this study suggest that herbalists are not 'calling out' for guidance, although there was also widespread reported interest in the study. With existing lack of overt guidance, evidence here suggests herbal texts are not influential, at least for HSE use. This is challenged in findings of

use from Steel et al. (2021) and Leach & Gillham (2011) concerning wider practice. Published guidance in the UK may therefore not be effective. Although obvious, a significant barrier to herbalists following guidelines could be actually reading them as found in Gyani et al. (2012). In addition evidence from the wider healthcare arena concerning adherence to guidelines is also mixed (Teeling et al., 2005), from positive engagement (Rebours et al., 2012) to limited engagement (Zadro et al., 2019). Important factors for effective guidelines have been identified in conventional healthcare review studies (Armstrong; 2003; Francke et al., 2008; Mostofian et al., 2015). Those appropriate for herbalists included development strategy, methods of dissemination that have multiple components, active education, guidelines that are easy to understand and carry out, with awareness of the existence of the guidelines, familiarity with content, and support with engagement. In conventional medicine the challenge to following guidelines is greatly increased by sheer numbers of guidelines. Taking into account these factors, it may be more possible to provide engaging support, as this appears complex.

The influence of other herbalists and herbalist seminars was strong (also found in Cunningham et al., 2019, Braun et al., 2013, Steel & Adams, 2011a:b) and lasting. The most effective approach within the context of providing guidelines may therefore be related to other herbalists formally sharing their own clinical evidence.

Considering most appropriate ways of sharing this information, although historically it has been experienced HSE-using herbalists treating people with 'serious' conditions who have been influential, other HSE users may also be valuable for informing HSE use related to more 'everyday' conditions as reported in the study. The constant reports between this study and Sprung (2016) that clinical evidence was important suggests the persistence of a large minority of herbalists who find HSEs clinically useful, indicating the existence of a potentially large amount of useful data. This suggests that non-HSE users may be 'missing out on' useful products. There may be 'prejudice' from non-HSE users that they are useful for 'serious' conditions only, which is not supported by research. However there is no evidence identified that peers are more influential than 'experts' or mentors, both being found influential in Cunningham et al. (2019). In Steel et al.'s (2021) of international naturopaths about 1/3rd reported sharing knowledge through CPD for other clinicians, suggesting a widespread readiness for engaging in sharing practice.

Since there are no strong identified feelings against HSE and widespread open-mindedness, with reduced historical controversy, this suggests that additional guidance from HSE users may be welcomed. It may be that the strong central focus on the WPE distracts herbalists from the use of preparations that may be of use but that they give little thought to.

It is hoped that limited moves towards collating clinical evidence to develop a database of case studies, associated with The Herbal Alliance (2021), will come to fruition. 'Practice based research networks' exist both in the conventional healthcare setting and in CAM, including in the integrative medicine setting as identified by Lee et al. (2019) and may offer a model to be adapted for WHM.

8.3.2 Supporting herbalists' engagement with research and the changing nature of training courses

Reports of widespread engagement with research, as well as HSE use, are important for informing those bodies supporting herbalist training and continued professional development. As pointed out by Lin et al. (2009) if the benefits of the EBM approach are to be realised fully, practitioners must be properly trained and participate in use and development of research studies, as also suggested by Snow et al. (2017). It is particularly important that herbalists are supported in this way, not simply to promote this aspect of the profession for its own sake, but because widespread engagement with and acceptance of research has been reported here already. Further training would address suggestions of variable research-literacy, un-critical and 'inappropriate' use (despite claims of research skills), as well as a proposed lack of awareness of contemporary objections to EBM methods in conventional healthcare settings. It is not clear whether increased research-literacy would increase the influence of research-based evidence, but mixed reports in New Zealand where research was strongly relied on in practice suggests that this is not a major factor in use (Cottingham et al., 2015). However, the apparent relative lack of influence on practice of a long history of training in research methods may inform providers of herbalist training and PAs, in terms of how this is provided. Support may be particularly useful for engaging herbalists with carrying out their own small-scale research which is not possible without research-literacy. It is important that herbalists add studies to the evidence base that better reflect UK WHM practice, such as case studies, which may encourage more meaningful integration of research and TK. In Steel et al.'s (2021) study of international naturopaths nearly 1/5th reported producing information to be shared in scientific journal articles suggesting that engagement with the research process is widespread. There is limited evidence in terms of the general aim in healthcare of how to increase research engagement and reduce the research-practice gap (Hickman et al., 2018); adoption of EBM methods in nurses has been found to be possible only if it is deemed useful for patients (Mathieson et al., 2019). Both training courses and PAs could look at how they actively support research development (as suggested by a survey respondent). For example the NIMH are currently engaging with The Herbal Alliance (2021) and NIMH members are welcome to contribute to projects (Appendix 15).

However, how this support would work is complicated by the fact that, despite readiness to use research, critical analysis and use of research studies by herbalists is limited by the majority having only having access to open access published articles. Wider access is limited to those who have institutional access, typically through university affiliation and this is very limited in the herbal community. This was mentioned by No. 6, and access to full text articles is noted as an important factor in facilitating the use of research evidence (Snow et al., 2017; Steel & Adams, 2011a;b; Steel et al., 2021). There is no obvious solution to this issue. In the past an online service called 'Greenfiles' located and shared details of recently published articles relevant to herbalists but this was limited limited to the abstract.

Support through training in research methods is also limited by the closure of all but one BSc training course (Lincoln University). Although BSc level training has been seen as necessary to reflect the professional nature of WHM (McCabe, 2008), closure of courses may have occurred due to increased student fees and the influence of the powerful skeptic lobby that does not consider WHM suited to BSc requirements (e.g. Nightingale Collaboration, 2021). In the place of BSc course other non-university based course have emerged (Heartwood Education, 2021a; Betonica, 2021 and The School of Herbal Medicine, 2021). It is not clear whether this will have an effect on HSE use (which is related to training in research methods here), as newly qualified herbalists join the profession from these newer schools. They were not represented in the survey data due to their recent introduction. Heartwood Education has a 'Research Methods' module in the first year of study but it does not specify an independent student research study module on its online course outline (Heartwood Education, 2021b) in the final year, as was standard for BSc degree courses. Indeed, conversely, Heartwood Education aims to be awarded university accreditation and there may be a resurgence in the drive towards university-affiliated education. Other PAs for natural health practitioners may also be moving in that direction; the British Association for Nutrition and Lifestyle Medicine (BANT, 2021) has only recently required university affiliated degrees for membership (Appendix 16). However, there remains a lack of research addressing herbalist or complementary medicine training in the UK and this is also limited elsewhere (Gray et al., 2019). Although there is some evidence that student attitudes in Australia favour a research-based EBM approach (Wardle & Sarris, 2014), there is a lack of similar data from the UK.

8.3.3 Defining WHM practice

Relatively uniform findings here of the focus on WPE and acceptance of research, with reduced HSE controversy are informative for supporting PAs and training courses in defining UK WHM practice and supporting practitioners. Indeed, representation of herbs may have been overshadowed somewhat by the historical emphasis on modernisation in terms of professional

skills and research (Waddell, 2016). These findings which emphasise the enduring importance of the WPE herbs and engagement with research may therefore inform organisations in supporting and representing herbalists more completely, given that the UK drive for regulation is now at least currently dormant. In addition, findings concerning the relationship between regulation and practice may inform this debate since it still continues outside the UK.

8.3.4 Implications for the wider interested community, including conventional healthcare

In addition to implications for herbalists, those for the wider interested community who use HSE or have an interest in WHM, may be rather different. The importance of these implications increases as the already large market for these products continues to increase (Hexa Research, 2021; Bitcon et al., 2016). The central finding of widespread HSE use by herbalists (albeit mainly *C. longa*) may be used to add weight to recommendations of OTC HSE preparations from the perspective of those involved in selling, recommending and purchasing these preparations, such as natural health practitioners, supplement companies and OTC retailers.

Other findings may be more informative in the wider healthcare arena, including conventional practitioners' attitude towards and acceptance of WHM, as well as informing training and clinical guidelines. Findings of overwhelming research acceptance by herbalists and widespread open-mindedness to HSE may be reassuring that the approaches of WHM and conventional medicine, often viewed as incompatible, may indeed share elements of a common language. This element of compatibility has been an important factor in the decades-long aim of 'modernising' WHM and findings may potentially support meaningful engagement of those in conventional healthcare with herbalists, which is limited (Owen and Lewith, 2004; Snow, 2016; Lin et al., 2009). Findings may help to change views of CAM being incompatible with EBM-based healthcare (Li et al., 2018a). Although evidence for attitudes of conventional health practitioners towards WHM is limited (Sharp et al., 2018b), there may be open-mindedness (Levine et al., 2003; Posadski et al., 2012; Jarvis et al., 2015; Soilemezi et al., 2020), but this interest may decrease with time qualified (Furnham & McGill, 2003; Abbott et al., 2011; Maha & Shaw, 2007); engagement through these findings may therefore be supportive. As barriers to this engagement with WHM may include the absence of reliable education (GMC, 2019; Soliman & Bilszta, 2021; Lorenc et al., 2014; Chang & Chang, 2015; Sharp et al. 2018a) despite calls for increased knowledge from practitioners (Patel et al., 2017; Owen & Lewith, 2004; Pirotta et al., 2000; Levine et al., 2003), it is proposed that health professionals may be open to the findings from this study that may encourage engagement particularly if academic weight and accessibility is added by publication in a peer-reviewed journal. In addition, awareness of the growing body of herbal research, including WPE studies,

as discussed here, may also be reassuring from the point of view of conventional healthcare practitioners or even private health funds, which are increasingly covering CAM modalities (Lin et al., 2009). A lack of research evidence, associated with widespread scepticism, has been a major issue in the development of links and engagement between conventional medicine and WHM/CAM, both at individual practitioner and organisational levels (Lorenc et al., 2014; Maha & Shaw, 2007; Patel et al., 2017). Facilitating changing perceptions of the evidence base for herbal medicine in mainstream healthcare may therefore be proposed to help overcome this significant barrier to integration in the UK NHS. Lin et al. (2009) found some support in the research for the benefits of naturopathy and WHM for almost all health conditions as early as 2003 and noted that CAM was one of the largest fields within the Cochrane Collaboration network. It is proposed that the current continually growing evidence base should be constantly re-appraised and although still limited in its support of WHM (Fisher et al., 2019) it cannot be ignored indefinitely in conventional healthcare. The aims of acceptance of and engagement of conventional healthcare provision with WHM, including training and clinical guidelines, have by no means been achieved (Sharp et al., 2018a; Chang & Chang, 2015; Soliman & Bilszta, 2021; Posadzki et al., 2012; Lorenc et al., 2014) particularly compared to the huge general public-driven market for herbal medicine (Evans, 2008; MacLennan, 2006; 2002; 1996; Hexa Research, 2021). This study may encourage the furtherment of these aims and support acceptance of WHM by conventional practitioners both directly and through training and clinical guidelines. However, a major barrier to engagement with herbal medicine in conventional healthcare may be the limited use of research evidence. Even though the body of herbal research has been continually growing, this called-for evidence to justify use in conventional medicine may have little influence if it is not accessed (Cunningham et al., 2019).

8.4 Suggestions for further research

This study has offered some insight into current and past HSE use in the herbal community, but raises questions and suggestions for further research. This concerns sharing clinical data, how widespread the use is of HSE herbs other than *C. longa*, the influence of herbal texts on practice, how research is accessed and research-literacy, the effects of regulation, how greater HSE use is integrated into practice, and herbal education.

As discussed above, there is the question of how to share the wealth of data from herbalists' own clinical practice that is not officially documented. There is a lack of guidance for choice of WPE or HSE whereas this study suggests that there is a large body of clinical evidence concerning these HSE herbs that may be investigated further. The Herbal Alliance (2021) is planning a facility for collection of herbalists' case histories. It is not yet clear how this will

progress and how the data may be used. Sharing such clinical information may support herbal practice, including choice of specific herb preparation and may also inform further research.

Since choice of preparation of these HSE herbs may be based on several factors that differ between the herbs, as discussed earlier, it would be informative to investigate the use of the individual herbs further. It is not known how widespread the use of HSE herbs other than *C. longa* are by herbalists; the author's previous study investigated use of *C. longa* only. It is not clear whether limited use of the HSE of these herbs compared to *C. longa* found here are due to reduced use in general or just reduced use of the HSE. Further research would be needed to investigate how widely used these other herbs are in herbal practice. Although they are commonly represented in herbal texts, suggesting widespread use, the influence of herbal texts in this study appears limited. It is not clear whether apparent lack of influence of texts is limited to choice of preparation of HSE herbs only as wider evidence suggests that texts are useful (Steel & Adams, 2011a; Leach & Gillham, 2011). Further studies may build on this initial insight into use of herbal texts and provide a more complete understanding of how they integrate with herbal practice. Texts may offer a range of information concerning herb use which includes traditional knowledge, research evidence, and recommended doses. Understanding more about use may offer further insight into attitudes, particularly towards dosing recommendations that are not readily justified.

Since there is little evidence of research evidence being clinically useful it is not clear how this relates to limited examples of herbs like *U. dioica* (nettle) root for which current use, as recommended in herbal texts, is at least partly based on modern research rather than TK. Further studies could offer an understanding of how herbalists integrate the use of such herbs with the supporting evidence rather than total reliance on TK.

Given that engagement with research has been found here to be so widespread, it is important to investigate further how and why this is happening. This is particularly important given suggestions of variable research-literacy and apparent lack of the long-standing controversy surrounding use of modern herbal research that largely does not reflect WHM practice. This would inform the debate around integration of research-based evidence and TK in WHM and also the controversy of EBM methods more generally in conventional healthcare; it is not clear whether herbalists are aware of these issues. Further research into how practitioners use research was also called for by Steel et al. (2021). There are many ways in which studies could be used. Direct access of journal articles may be of the full text or abstract only, depending on access. Links to research may be sent from organisations or individuals and summaries of the research (not all peer reviewed) may be found in herbal texts, seminars or other forms of information. Or accessing research may imply uncritical acceptance of the body of evidence or

general acknowledgement that the research exists (as suggested in the author's previous study) where the very size of the body of research may be taken to indicate efficacy. Since there appears to be widespread engagement but without 'integration' with practice it would be useful to investigate what kind of alternative research herbalists would find clinically informative, for example based on case-studies.

Investigation into the proposed renewed WPE focus here after the end of the drive towards regulation would also be informative, including more widely given the ongoing regulatory focus in other countries where WHM is practiced (Ng, 2020; Ooi et al., 2018; Cottingham et al., 2015). Research could investigate attitudes towards regulation and how this has affected or affects practice.

It is not clear how HSEs and WPEs are integrated into practice and questions have been asked here about whether full integration is possible, whether herbalists can simultaneously 'commit' to both of the contrasting underlying philosophies. Research that focuses on the practice of those herbalists who regularly use multiple HSEs may offer a greater understanding of the nature of such apparent integration that is as yet unclear.

There is no published research concerning UK herbalist training programmes and differences have been found here between herbalists attending different courses. Investigation could offer further evidence of how herbalists are influenced by their training and what they seek from it. This may concern issues raised here such as the focus on research, open-mindedness to HSE, and focus on WPE.

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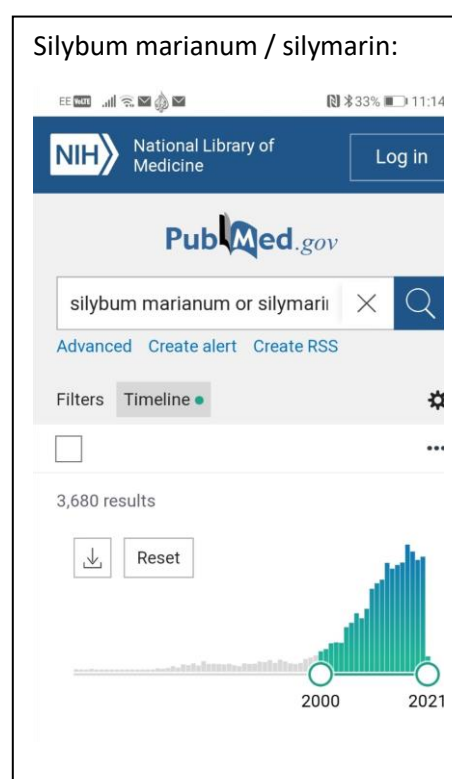
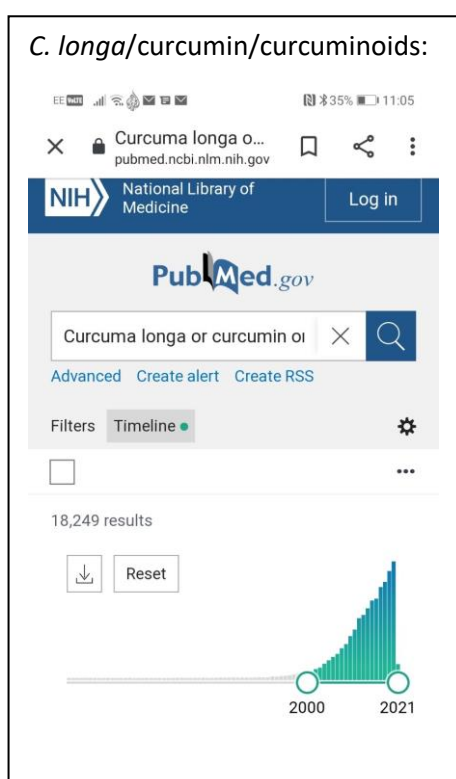
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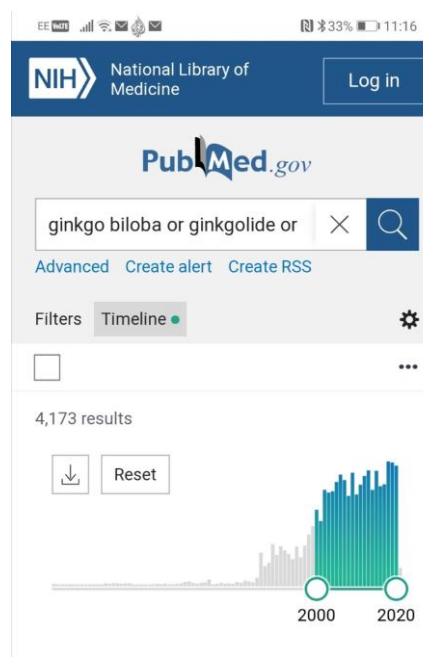
Appendices

Appendix 1: Diagrams of timelines from PubMed to show the large increase in published studies on a range of HSE and WPE herbs (including major active constituents where identified) over the last 20 years.

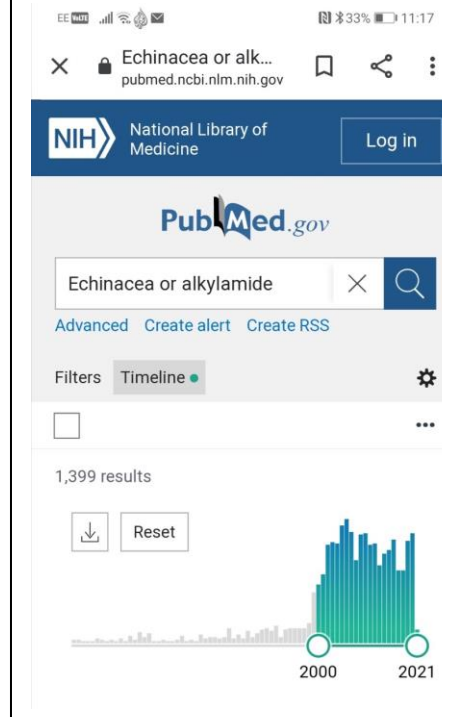
Searches show that research on HSE herbs *C. longa*, *S. marianum* and *Boswellia serrata* is increasing particularly quickly but the same is also true for some common WPE herbs like *Z. officinale*, *M. recucita* and *C. asiatica*. In addition, RCTs on popular WPE herbs like *H. perforatum*, *Z. officinale* and *Echinacea* spp. are similar in number to HSE herbs.

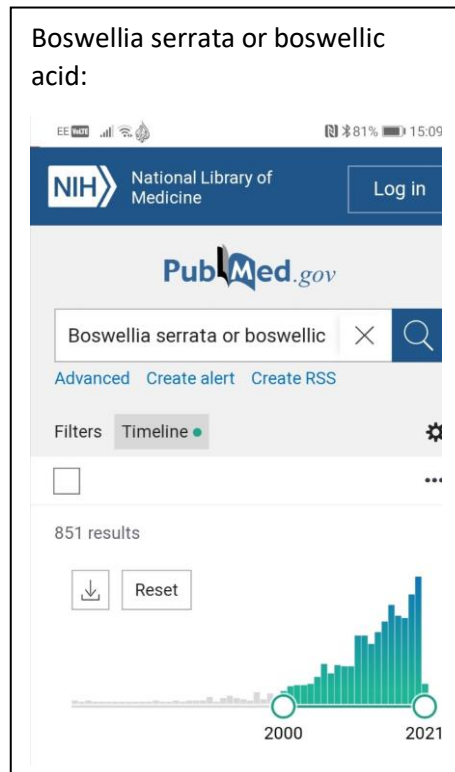
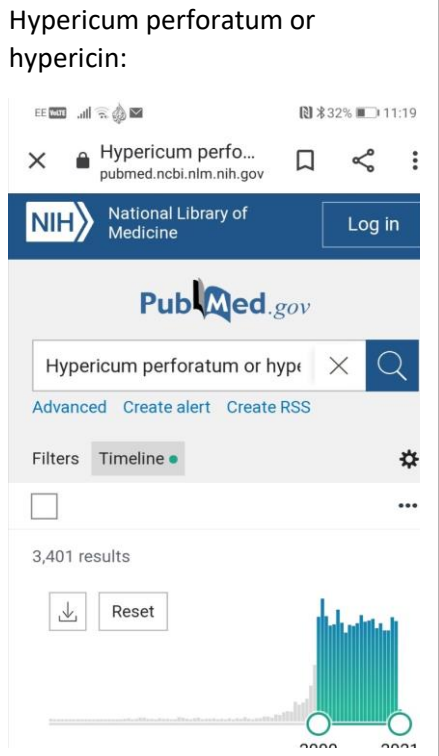


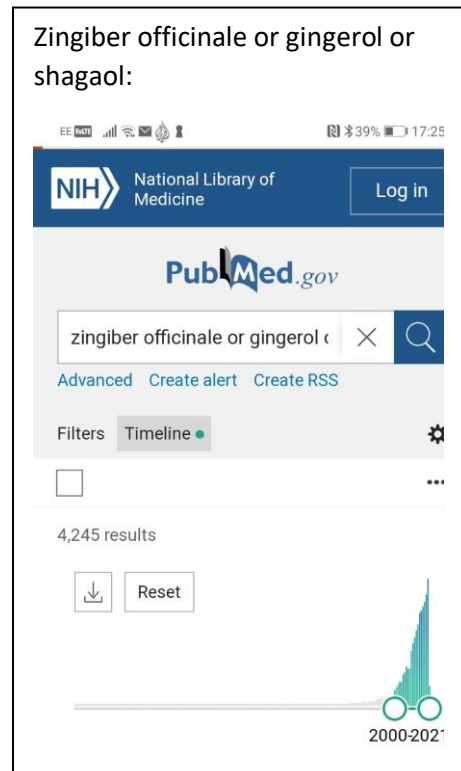
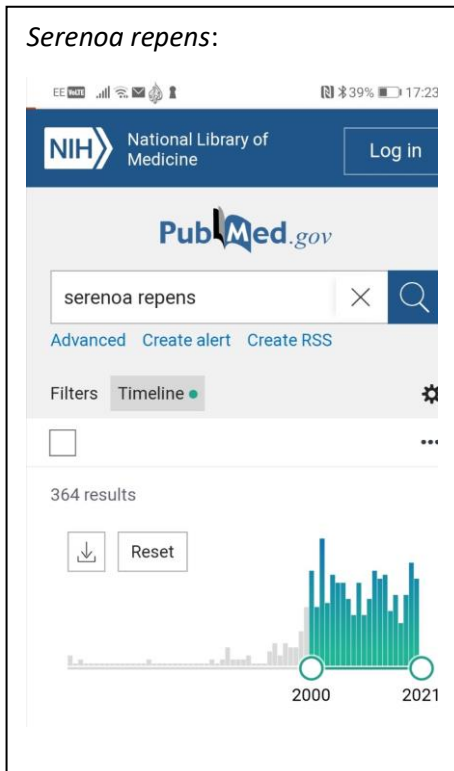
G. biloba or *G. bilobalide* or bilobalide:

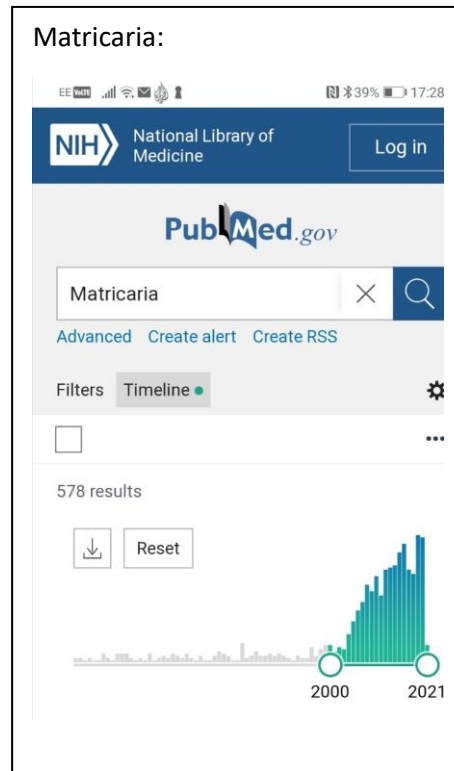
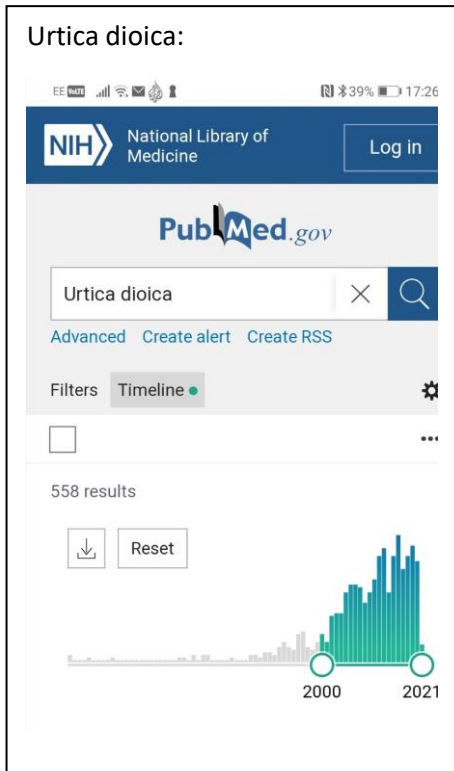


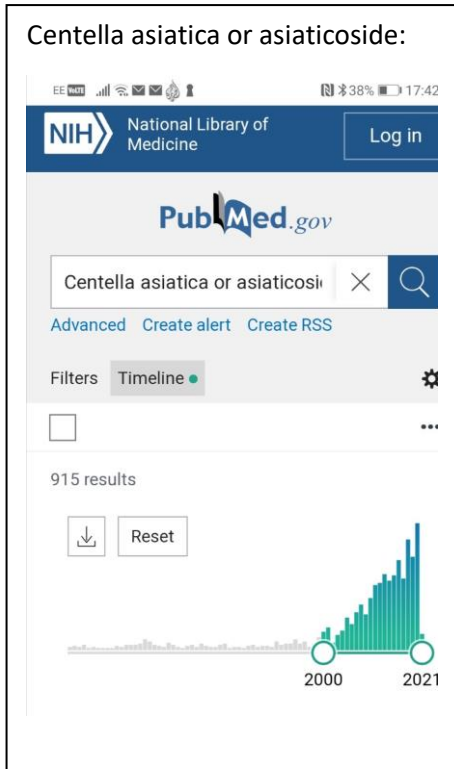
Echinacea or alkylamide:



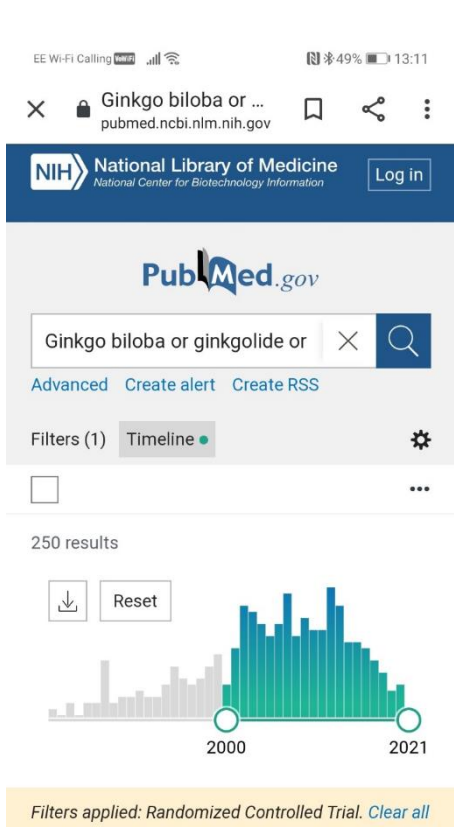








Appendix 1a: Pubmed timeline showing recent reduction in research ‘interest’ in RCTs for *G. biloba* compared to *C. longa* and lack of increase for *S. marianum* and *S. serrulata*



EE Wi-Fi Calling 63% 14:20

Curcuma longa or...
pubmed.ncbi.nlm.nih.gov

Prevention and treatment information (HHS)
Español

NIH National Library of Medicine
National Center for Biotechnology Information Log in

PubMed.gov

Curcuma longa or curcumin or

Advanced Create alert Create RSS

Filters (2) Timeline

344 results

Reset

1980 20 Back to Top

Filters applied: Randomized Controlled Trial, Humans. Clear all

EE 15% 16:34

serenoa serrulata...
pubmed.ncbi.nlm.nih.gov

Prevention and treatment information (HHS)
Español

NIH National Library of Medicine
National Center for Biotechnology Information Log in

PubMed.gov

serenoa serrulata

Advanced Create alert Create RSS

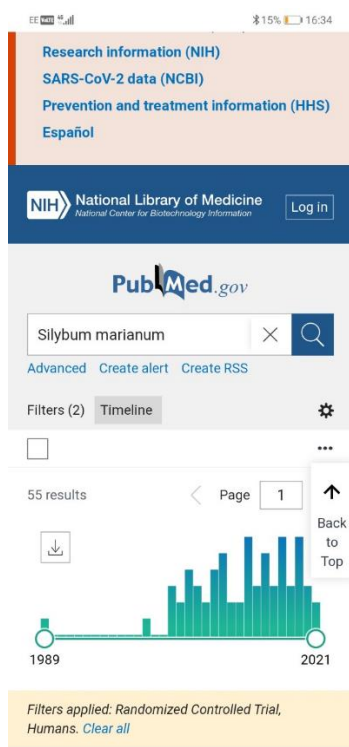
Filters (2) Timeline

72 results

Page 1

1992 2021

Filters applied: Randomized Controlled Trial, Humans. Clear all



Appendix 2: Table showing numbers of published ‘human randomised controlled trials’ on PUBMED. As of 3.1.21, numbers of studies found for a range of herbs and their major active constituents (if any specifically identified)

Search terms (Latin name of plant and major identified active constituents)*	No of total results on PubMed	No of relevant studies located on active constituents or HSE on PubMed with ‘Human Randomised Controlled Trial’ filters	No of relevant studies located on WPE on PubMed with ‘Human Randomised Controlled Trial’ filters
Herbs that are commonly available as HSE products			
<i>Curcuma longa</i> or curcumin or curcuminoid	18,900	316	20
<i>Ginkgo biloba</i> or bilobalide or bilobalide	4462	327	3

<i>Silybum marianum</i> or silymarin or silibinin	4580	123	0
<i>Boswellia serrata</i> or boswellic acid	684	54	2
<i>Serenoa serrulata</i> or <i>repens</i>	423	93	0
Herbs that are not commonly available as HSE products			
<i>Aesculus hippocastanum</i> or escin or aescin	1403	34	10
<i>Arctium lappa</i>	400	0	5
<i>Ballota nigra</i>	24	0	0
<i>Berberis vulgaris</i> or berberine	6311	77	2
<i>Centella asiatica</i>	895	0	40
<i>Echinacea</i> or alkylamides	1626	1	58
<i>Eleutherococcus senticosus</i>	652	0	31
<i>Glycyrrhiza and glabra</i> or glycyrrhizin	784	19	18
<i>Hypericum perforatum</i>	3025	0	149
<i>Matricaria chamomilla</i> or <i>matricaria recucita</i>	653	0	27
<i>Paeonia lactiflora</i> or <i>paeoniflora</i> or paeoniflorin	1443	0	19
<i>Rosmarinus officinalis</i> or Rosmarinic acid *	3143	3	17
<i>Taraxacum officinale</i>	781	0	5
<i>Thymus vulgaris</i> or thymol	770	16	11
<i>Urtica dioica</i>	642	0	24
<i>Withania somnifera</i> or withanolides	1685	0	25
<i>Zingiber officinale</i> or gingerol or shagaol	4542	1	221

. * There are many constituents that are found in more than one plant, such as rosmarinic acid, but they are included if they are major constituents.

Appendix 3: Table to show recent reviews and meta-analyses for *C. longa* 2020-21

Reference	Detail of Study on HSE RCTs	Findings
Paultre et al., 2021.	Systematic review, 10 RCTs	Osteoarthritis: effects are similar to that of NSAIDs
Wang et al., 2021a	systematic review and meta-analysis of 16 RCTs	Osteoarthritis: showed a comparable effect to NSAIDs
Chandan et al., 2020	systematic review and meta-analysis of 7 curcumin RCTs	Ulcerative colitis: 'combined mesalamine and curcumin therapy was associated with roughly threefold better odds of a clinical response compared to placebo'
Fusar-Poli et al., 2020	meta-analysis of 9 RCTs	Depression: curcumin 'might improve depressive and anxiety symptoms in people with depression'.
Baziar & Parohan, 2020	A systematic review and dose-response meta-analysis of 8 RCTs	NAFLD: curcumin supplementation might have a positive effect on visceral fat and abdominal obesity that have been associated with NAFLD.

Coelho et al, 2020	Systematic review of 6 RCTs	Ulcerative colitis: 'Studies show that curcumin may be a safe, effective therapy for maintaining remission...when administered with standard treatments'
Fernández-Lázaro et al., 2020.	Systematic review of 11 RCT	Inflammation and oxidation: 'curcumin at a dose between 150-1500 mg/day before and during exercise, and up until 72 h' post-exercise, improved performance by reducing exercise-induced muscle damage and modulating the inflammation caused by physical activity'
Wang et al., 2021b.	Systematic review and meta-analysis of 10 trials	Depression: evidence quality is low
Mansouri et al., 2020	Systematic review 22 RCTs	Cancer: curcumin reduces the side effects of chemotherapy or radiotherapy, resulting in improving patients' quality of life. A number of studies reported that,

		curcumin has increased patient survival time and decreased tumor markers' level.
Jalali et al., 2020.	9 RCTs	Non-Alcoholic fatty liver disease: curcumin supplementation has favourable effect on metabolic markers and anthropometric parameters in patients with NAFLD.
Goulart et al., 2020	Systematic review and meta-analysis (abstract access only)	curcumin can help in the induction of remission in UC subjects.
Zheng et al., 2020.	Meta-analysis of 6 RCTs	Curcumin, as an adjuvant treatment of mesalamine, was proved to be effective and safe in ulcerative colitis

Appendix 4: Table showing GP interview study analysis

First results from a PubMed search of 'GP' and 'interviews' or 'herbalist' and 'interviews' carried out when the author was first investigating methodology. GP studies were chosen as an appropriate alternative healthcare professional to herbalists. Suitable studies were those that used interview techniques and for which details of the study could be accessed. The first 12 such studies indicated that for interview studies in the healthcare arena, the most common analysis methodology is based on thematic analysis.

Study	Participants and location	Design	Analysis	General Aims
Ryves et al., 2016	England, 32 GPs	Qualitative, semi-structured telephone interviews	Thematic analysis	Identify views and understanding of delayed antibiotic prescribing
Hjordahl et al., 2016	Norway, 24 GPs	Qualitative Focus group interviews	Thematic analysis as described by Braun & Clarke, 2006	Exploring GPs attitudes toward participating in emergency medicine
Hvidt et al., 2016	Denmark; 31 GPs	Qualitative semi-structured focus group interviews	Thematic analysis (as per Bernard & Ryan, 2009)	How GPs understand the existential dimension, when and how it is addressed with patients
Fletcher-Lartey et al., 2016	Australia; 584 GPs questionnaire survey; 32 GPs interviewed	Quantitative postal questionnaire and qualitative semi-structured interviews	Framework analysis	To explore the management of urinary tract infections by GPs
Latif et al., 2016	England; 11 GPs and 47 pharmacists	Qualitative semi-structured interviews	Thematic analysis, guided by Damschroder's consolidated framework for	To explore the complex 223errulate involved in the implementation of a new service

			implementation research	
Dutton et al., 2016.	Australia; 9 GPs and 10 practice nurSEs	Qualitative semi-structured interviews	Content analysis following the framework analysis approach (Ritchie, Lewis. Qualitative Res Practice, 2003)	Exploration of acceptability of physical activity assessment instrument
Bless et al., 2016.	Switzerland; 69 GPs recruited by post and telephone follow-up	Qualitative semi-structured face-face interview, repeatedly adapted to capture emerging themes; informed by objectives, expert opinions and literature	Inductive content analysis as required by GT	To investigate case management of gastroenteritis patients
Fleischmann et al., 2016	Germany; 30 GPs recruited by post and existing networks	Qualitative open guideline interviews	GT	Explore experiences and expectations re interprofessional collaboration
Molin et al., 2016	Denmark; 8 GPs recruited through existing networks and programs	Qualitative semi-structured interviews	Thematic analysis in 6 phases as per Braun & Clarke, 2006	To investigate GPs perceptions of their role with COPD* patients

Van Gaalen et al., 2016	Netherlands; patients, GPs nurses	10 Focus groups and 12 semi-structured interviews	Directed content analysis	To explore barriers to self-management
Garth et al., 2016	Australia; 80 GPs and other health professionals	Qualitative focus groups and semi-structured interviews	Thematic analysis using template analysis	To examine perceived utility of learning plans in training
Duane et al., 2016	Ireland; 7 GPs and 14 patients	Semi-structured interviews, face-face and telephone	Framework analysis	Exploring experiences of delayed antibiotic prescribing for UTIs

Appendix 5: Examples of memos from the initial interview stage

25.1.2019

Little response to requests

Disappointing response to online requests for interview. Thought that people would be quicker to volunteer for an interview, particularly since I've repeated posts and begged as herbalists online usually engage readily. Maybe they think other people will do it, or they don't like the topic, but last survey was a good response so not likely. Herbalists I've spoken to about the study have all been positive but it hasn't resulted in arranging interviews. It maybe needs a more pro-active approach, which I am not confident about as I don't want to hassle people. Maybe the topic is not that engaging or perceived as important.

24.2.19

Recruitment

Several people have expressed interest and then not replied after I sent the documents and consent which is frustrating but have had difficulty with the opening of documents and the

consent form which I fear put people off. Maybe I should have followed up non-response more but I don't want to hassle people.

Date: 6.6.19

How much HSE used

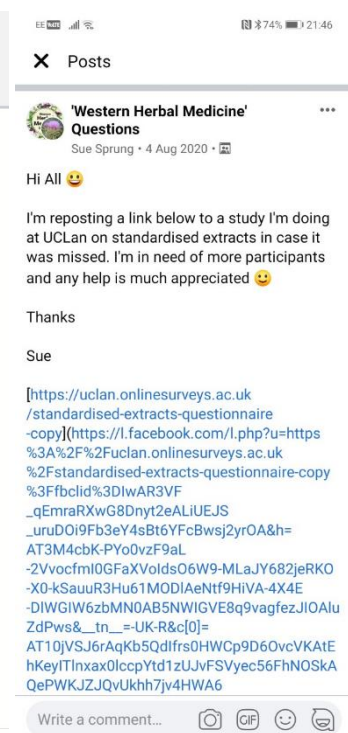
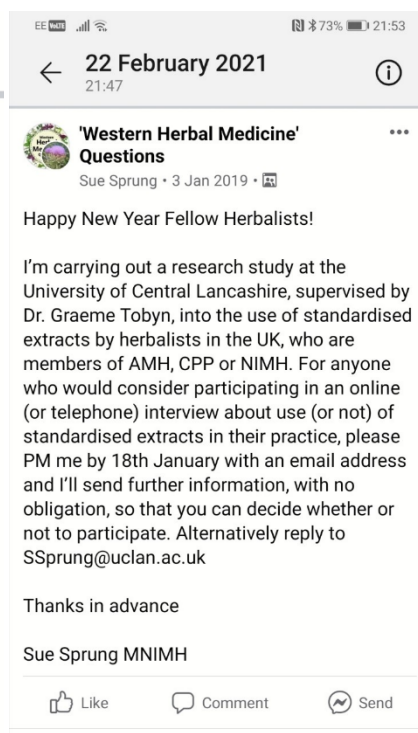
First volunteers for interview do not use HSE which is surprising given high use from last time. Maybe users do not want to talk about it or has use reduced? Are users too busy to take part? Need to find more users.

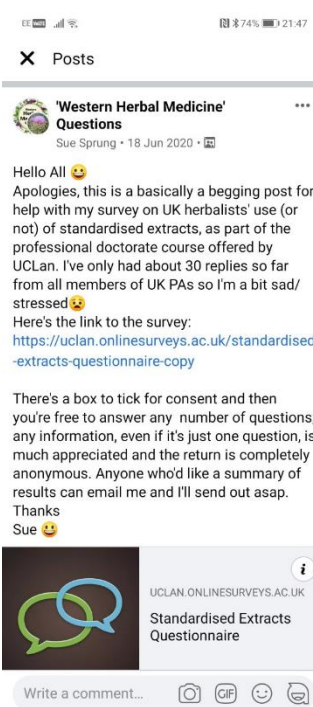
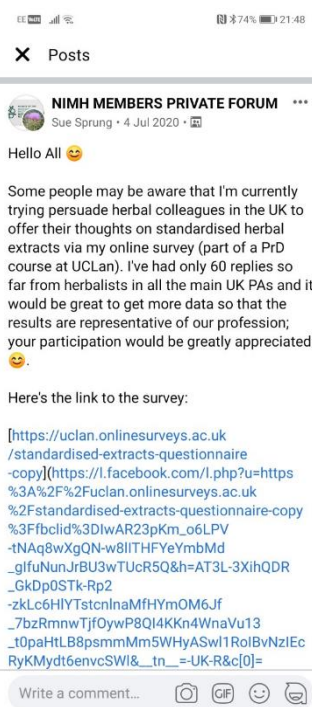
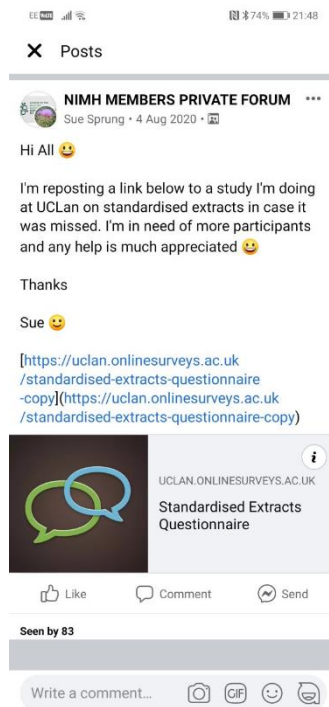
6.6.19

No HSE users in first interviews

First volunteers for interview do not use HSE which is surprising given high use from last time. Maybe users do not want to talk about it or has use reduced? Are users too busy to take part? Need to find more users.

Appendix 6: Requests on Facebook pages for interview participants and electronic link to the survey





Appendix 7: Invitation email, information sheet and consent form for prospective interview participants

Invitation email

Title: Interview about standardized extracts

Dear [name of MH]

Thank you for considering taking part in an interview to investigate attitudes towards standardized herbal extracts.

Please find attached an information sheet with details of this study. After reading this, I'd be grateful if you would reply to this email to either confirm or decline giving your consent to take part in an interview. If you decide to give your consent, please be aware that the interview will be recorded.

Many thanks for your time, help and co-operation and please feel free to contact me if you have any questions.

Yours sincerely,

Sue Sprung

Researcher

Sue Sprung MNIMH
6 Cleveley Park
Liverpool
L18 9UT

Tel: 0151 2814648

Email: SSprung@uclan.ac.uk

Supervisor

Graeme Tobyn, FNIMH
Senior Lecturer, School of Community Health
and Midwifery,

College of Health,

University of Central Lancashire
Preston PR1 2HE

Email: Gtobyn@uclan.ac.uk

Information Sheet

Information Sheet:

Interviews of Herbal Medicine Practitioners – Attitudes towards standardized extracts

Introduction

Thank you for considering taking part in an individual interview about use of herbal standardized extracts. The following information about the study is provided to enable you to decide if you would like to take part.

Background

This study forms part of the Professional Doctorate in Health that I am undertaking, though the University of Central Lancashire (UCLan) and supervised by Dr. Graeme Tobyn (http://www.uclan.ac.uk/staff_profiles/graeme_tobyn.php). I am a practising medical herbalist and NIMH member since 2010.

Aims of the study

The study I am carrying out aims to investigate how professional herbalists have arrived at decisions about the use of standardized extracts in practice; the data obtained will be used to further the debate about standardized extracts and share practice amongst medical herbalists and the wider interested community.

What will I be asked to do?

The interview will preferably take place, at your convenience, online via the UCLan server and video recorded. If preferred, just an audio recording facility can be used; if so please fill in the consent form accordingly, by not signing the box labelled 'I agree to the interview being video recorded'. The time allotted to the interview is not fixed but will be a maximum of 45 minutes; within this limit, you are free to take as short or as long a time as you prefer to answer the questions.

What are the risks or benefits of taking part

You have been approached to take part because you are a qualified herbal practitioner and member of a UK professional body. There are no significant risks to you associated with participation in the study, although normal rules for safeguarding and Professional Standards

apply and appropriate bodies will be contacted as necessary. Your participation is entirely altruistic and is intended to support herbal practice. You will be asked in the interview if you wish a summary of the findings to be forwarded to you, and the entire study will be published as soon as possible.

Anonymity and confidentiality of data

If you decide to take part in the interview, all the information you supply will be anonymised in the final report and it will not be possible to identify from whom the comments originated; you will also be asked to avoid providing information, about you or your practice, that may risk your identification in the final report. No identification of individuals will be possible in the final report and no personal or identifiable details will be included. Interview data will be anonymous and only linked to an identifying email address via a numerical identifier for 6 weeks after the interview; after this time the email identifier will be removed and withdrawal will no longer be possible. Data will be treated confidentially and will only be accessible to the researcher and supervisory team. Interviews will be recorded on the secure UCLan server, will be immediately transcribed and the original recording deleted.

Personal data, held securely, will consist of signed consent forms and electronic contact details; consent forms will be kept in a locked filing cabinet in the UCLan office and destroyed after the research has been completed and the findings disseminated. Electronic contact details will be stored on the password-protected UCLan server until the study has been completed and approved, so that a summary can be sent to you. However, if you do not wish to receive a summary, your contact details will be deleted 6 weeks after the interview; you will be asked for your preference at the end of the interview. Electronic, anonymised interview data will be stored securely on the UCLan password-protected server for 5 years and all data will be accessible only to Sue Sprung and the supervisory team. Although data is treated confidentially, please be advised that if anything of concern is disclosed it may be appropriate to report it firstly to my supervisor and/or the relevant professional body.

What if I change my mind about taking part?

You can withdraw from the study up to 6 weeks after the interview, by contacting Sue Sprung or supervisors using the contact details below and your interview data and contact details will be deleted.

What will be done with the results?

This study is being undertaken at the University of Central Lancashire. I plan to submit the findings for publication in a peer-reviewed journal, circulate the findings in newsletters of professional associations and present the findings at herbalists' professional body conference/s.

Research ethics

This study has received ethical approval from the STEMH review panel, project number 947, at the University of Central Lancashire.

What do I do now?

If you would like to take part in this study, please print out, complete and sign the attached consent form and post to the address below; please request a pre-paid postage label, if required, by emailing Ssprung@UCLan.ac.uk. Please reply by 26/02/2019.

Contact details for further questions

I am happy to answer any questions that you might have about this study in order to decide whether to give consent. For further information, you can contact either me, or my supervisors:

Researcher

Sue Sprung MNIMH, C/O Dr. Graeme Toby
School of Community Health and Midwifery,
College of Health,
Brook Building BB323
University of Central Lancashire
Preston PR1 2HE

Tel: 0151 2814648

Email: SSprung@uclan.ac.uk

Supervisors:

Dr. Graeme Toby Senior Lecturer, School of Community Health and Midwifery,	Prof. Paul Rutter Professor of Pharmacy University of Portsmouth St Michael's Building	DR. KATE CHATFIELD Deputy director of the centre for professional ethics School of Health Sciences
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College of Health, Brook Building BB323 University of Central Lancashire Preston PR1 2HE Email: GWTobyn@uclan.ac.uk	White Swan Road Portsmouth PO1 2DT Paul.Rutter@port.ac.uk	University of Central Lancashire Brook Building, BB424 +44 (0) 1772 89 3697 kchatfield@uclan.ac.uk
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If you have any concerns, please contact:

University Officer for Ethics:

University of Central Lancashire

Preston

PR1 2HE

Tel. 0044 1772 89 3700

Email: OfficerForEthics@uclan.ac.uk

Thank you for taking the time to read this information and considering taking part.

Consent form for interview participation



CONSENT FORM

Study Title: Standardised Extracts – Is UK Herbal Medicine practice following the research?

Student Researcher:

Name – Susan Sprung

Email – Ssprung@uclan.ac.uk

Address – School of Community Health and Midwifery, College of Health, University of Central Lancashire, Preston. PR1 2HE

Please read the following statements and put your initials in the box next to statements that you consent to; for any that you do not give consent to, please leave blank

I confirm that I have read and understand the information sheet, dated 14/02/2019 for the above study and have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
---	--

I understand that my participation is voluntary and that I am free to withdraw, up to 6 weeks after participating in an interview, without giving a reason.	
---	--

I agree to take part in the above study.	
--	--

I understand that it will not be possible to withdraw my interview data from the study 6 weeks after the interview has been undertaken, as it will be anonymised	
--	--

I agree to the interview being audio recorded	
---	--

I agree to the interview being video recorded (do not initial this box if you prefer audio recording only)	
---	--

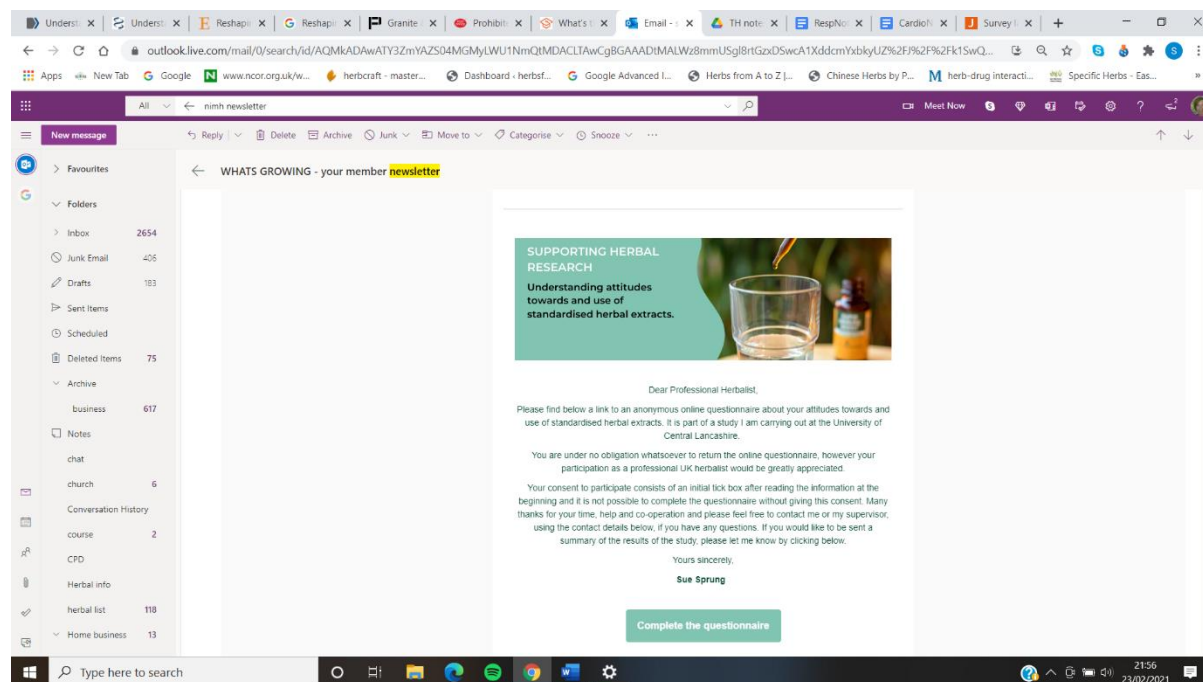
I agree to the use of anonymised quotes in publications	
---	--

Name of Participant:	
Date:	
Name of Researcher:	Sue Sprung
Date:	

Please return this consent form by email to SSprung@UCLan.ac.uk or alternatively to the address below:

Sue Sprung, C/O Dr Graeme Tobyn
School of Community Health and Midwifery, College of Health,
Brook Building BB323
University of Central Lancashire,
Preston. PR1 2HE

Appendix 8: Example of introductory message and online link sent to NIMH members via monthly newsletter



Appendix 9: Details of agreement from CPP, AMH, ANP, URHP, NIMH to send survey to members

Pamela Bull <pamela.bull@btopenworld.com>

Wed 08/01/2020 12:42

Good Morning All.

I have permission to send to you the undermentioned questionnaire put together by Susan Sprung concerning research she is doing at the University of Central Lancashire into professional herbalists' use of standardized extracts. The study is part of a professional doctorate in health at UCLan.

Pam

Shelley <shelley@shs100.com>

Mon 06/01/2020 13:41

Hi Sue

Thank you for your enquiry.

I have emailed your questionnaire to the AMH council and once approved I will forward on to our Practitioner members.

Kind regards

Shelley Day

AMH General Secretary

Hello Sue,

I hope you're well!

Yes more than happy to support this if we can. If you could send me more details as and when you have them, I'll follow up with you.

Warm regards

Elizabeth Wright

President | Association of Naturopathic Practitioners

www.theanp.co.uk

04/03/2020 12:46



● SUESPRUNG@hotmail.com

□
Hello Sue,

Having forwarded on your message to our president and heard back from her, I can confirm we'd be very happy to forward a questionnaire link on to our members. I'll send it and any accompanying message on as soon as possible after receiving them.

All the best,

Cassie Sherriff

URHP Information Officer

James Wiltshire <james.wiltshire@nimh.org.uk>

Tue 21/04/2020 11:27

-
-
-
-
-

- Susan Sprung

□
Hi Sue

Very happy to get this out to members for you.

If you could send details of the questionnaire along with a copy of the approval for our records then I'll get it sent out.

All the best

James

Appendix 10: Main interview question and proposed secondary questions

Main question:

How did you come to use HSE (or not) in practice?

Support questions:

When and how did you first become aware of HSE products?

What was the most important factor that influenced your use of HSEs (or not)?

What other factors influenced your use of HSE (or not)?

What would cause you to use HSEs more frequently?

What would cause you to use HSEs less frequently?

Do you use HSEs?

What do you use HSEs for?

and WPE of the same plant for different reasons?

What are the benefits of using HSE in your clinical practice?

Appendix 11: Studies involving surveys of practitioners of western herbal medicine and GPs

PubMed was searched using search terms ‘herbal medicine’, ‘herbalist’, ‘GP’, ‘practitioner’, ‘survey’ and ‘questionnaire’.

Postal Studies:

Study	Survey Design	Recruitment of practitioners	Response rate & Comments
Casey et al., 2007; 2008	Postal survey. Distributed with NHAA professional journal over 2 issues.	All full members of the National Herbalists' Association of Australia (NHAA) (n=649)	58.2% (n=378) High response rate despite complex open questions – perceived as important as sent by NHAA
Nissen, 2010	Anonymous, postal survey. 31 closed and open-ended questions, 4 pages	Sample of NIMH practitioners (5 regions); unclear how practitioners identified (n=188)	29% (n=55) Reasonable response rate despite some open-ended questions and no follow-ups
Frost et al., 2014	2-sided A4 survey; all close-ended questions. Follow-up surveys sent to non-responders.	All UK members of NIMH, CPP and AMH with viable practice addresses (n=598)	40% (n=239) Good response rate. may be related to closed-ended questions and strategies to maximise response. Prepaid return, university-headed paper, personalised letters

Online studies:

Brock et al., 2014	Email survey, with 2 follow-ups, oral alert at NIMH conference and advert in NIMH newsletter. Mostly open-ended questions	All members of NIMH with identifiable email addresses. (n=377)	16% (n=62) Low response rate, despite follow-ups and prompts via NIMH. Due to demanding open-ended questions?
Rooney and Pendry, 2014	Brief online survey, 11 open and closed questions via www.surveygizmo.com . University affiliation.	email contacts on NIMH register (n=428)	17% (n=72) Low response rate.)
Corp and Pendry, 2013	Short survey, 10 closed, 1 open and 2 mixed questions. Surveys were sent via www.surveygizmo.com and via post with prepaid return University affiliation	NIMH register, email contact with link to online survey (n=470); further contacted by post (n=61). total (n=531)	26.7% (n=142)
NIMH, 2019 (unpublished)	27 point survey consisting of closed questions and open comment box at the end via SurveyMonkey	653 NIMH members, present, past and student	32% (n=206)
NIMH, 2018 (unpublished)	Short online 11 point survey, with closed questions and open comment box at the end via SurveyMonkey	561 NIMH members surveyed	18% (n=98)

Standardised Extracts Questionnaire

Information

IMPORTANT INFORMATION, PLEASE READ

Survey of Herbal Medicine Practitioners: Attitudes towards standardized extracts

Introduction

Thank you for considering participating in this questionnaire study about UK Professional Herbalists' use of herbal standardized extracts. The following information about the study is provided to enable you to decide if you would like to take part.

Background

This study forms part of the Professional Doctorate in Health that I am undertaking, through the University of Central Lancashire (UCLan) and supervised by Dr. Graeme Tobyn (http://www.uclan.ac.uk/staff_profiles/graeme_tobyn.php). I am a practising medical herbalist and NIM member since 2010.

Aims of the study

The study I am carrying out aims to investigate how professional herbalists have arrived at decisions about the use of standardized extracts in practice; the data obtained will be used to further the debate about standardized extracts and share practice amongst medical herbalists and the wider interested community.

What am I required to do?

Participation requires you to complete this online questionnaire. On the next page you will find a consent form and, if you consent, you will be able to access the questionnaire.

The questionnaire consists of a maximum of 28 short questions, most of which are optional. The questionnaire should take 10-20 minutes to complete, depending upon how much you choose to write. Your completed questionnaire is submitted completely anonymously by clicking the 'finish' button.

What are the risks or benefits of taking part

You have been approached to take part because you are a qualified herbal practitioner and member of a professional body. There are no significant risks to you associated with participation in the study and you are under no obligation whatsoever to complete the questionnaire. Your participation is entirely altruistic and is intended to support herbal practice. If you wish to be sent a summary of the study findings please send your request by email to SSprung@uclan.ac.uk.

Anonymity and confidentiality of data

The questionnaire is completely anonymous and it is not possible to identify you from your returned questionnaire, however you are requested to avoid providing any information about you, your practice, any other practitioner, that may risk identification of individuals. No identification of individuals will be possible in the final report and no personal or identifiable details will be included.

Anonymous electronic questionnaire data will be stored securely on the UCLan password-protected server for 5 years and all data will be accessible only to Sue Sprung and the supervisory team.

What if I change my mind about taking part?

Please be aware that once the questionnaire has been returned by clicking the 'finish' button it is not possible to withdraw your data from the study due to the anonymous nature of the return. Withdrawal is possible at any point before clicking on the finish button; no data will be submitted or saved until the finish button has been clicked and closing the browser will enable exit from the survey without submitting any information.

What will be done with the results?

This study is being undertaken at the University of Central Lancashire. I plan to submit the findings for publication in a peer-reviewed journal, circulate the findings in newsletters of professional associations and present the findings at herbalists' professional body conference/s.

Research ethics

This study has received ethical approval from the Health Review Panel, project number 947, at the University of Central Lancashire.

What do I do now?

If you would like to take part in this study, please access, complete and return the online questionnaire by 31/06/2020.

Contact details for further questions

I am happy to answer any questions that you might have about this study in order to decide whether to consent. For further information, you can contact either me, or my supervisor:

Researcher

Sue Sprung MNIMH (C/O Dr Graeme Tobyne)
University of Central Lancashire
Preston PR1 2HE
Tel: 0151 2814648
Email: SSPrung@uclan.ac.uk

Supervisor

Dr Graeme Tobyne
Senior Lecturer, School of Community Health and
Midwifery,
University of Central Lancashire
Preston PR1 2HE
Email: GWTobyne@uclan.ac.uk

If you have any concerns, please contact:

University Officer for Ethics:

University of Central Lancashire
Preston
PR1 2HE

Tel. 0044 1772 89 3700

Email: OfficerForEthics@uclan.ac.uk

Thank you for taking the time to read this information and considering taking part.

Consent Page

I confirm that I have read and understand the participant information provided for this study.

I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

I understand what is required of me for the research project.

I understand that my participation in this study is voluntary, and I am free to withdraw at any time without giving any reason while I am completing the survey. However, once the survey has been completed it will not be possible to isolate and extract my responses.

I understand that the information I provide is completely anonymous so that it cannot be traced back to me as an individual. The information will be retained on the researcher's password protected computer for 5 years in accordance with the university policy.

I understand that quotations from some of my responses may be used in the write up of this project but they will not be attributable to me.

1. I consent to participate in this study and with this agree to the conditions listed above. *Required*

Agree and continue

Disagree and end

Use of standardised extracts

Please note: This questionnaire is for professional herbalists in the UK about use of highly standardised herbal extracts in practice.

The term 'standardised extract' in this questionnaire refers to those products that are purposefully produced to provide a high percentage of one particular constituent or group of constituents compared to the percentage in a whole plant extract, whilst acknowledging that all plant preparations are on a spectrum of levels of manipulation. Common examples relevant here are an extract of turmeric with a high percentage of curcumin/curcuminoids or an extract of milk thistle with a high percentage of the silymarin complex. In this instance, the term 'standardised extract' does not include those whole plant extracts which may be called 'standardised' and guarantee a minimum percentage of a constituent, but have not been specifically produced to maximise that constituent compared to other constituents in the plant.

2. Do you currently use any highly standardised herbal extracts in practice (e.g. products based on curcumin, silymarin)? *Required*

- Yes
- No

Reasons for not using standardised extracts

3. Please give reason/s for not using standardised extracts

Previous use

4. Even though you don't currently use standardised extracts in your practice, have you done so in past?

- Yes
- No

Which products

5. Please specify which standardised extract/s you used to use in practice.

Standardised extracts used in practice

6. Please specify which standardised extract/s you currently use in practice.

Influences on using standardised extracts

7. Please select the importance of the influences below on your decision to use standardised extracts. Please don't select more than 1 answer(s) per row.

	Strong influence	Moderate influence
Published research paper/s	<input type="checkbox"/>	<input type="checkbox"/>
Recommendation from another herbalist	<input type="checkbox"/>	<input type="checkbox"/>
Seminar by another herbalist	<input type="checkbox"/>	<input type="checkbox"/>

Seminar by supplement company	<input type="checkbox"/>	<input type="checkbox"/>
Evidence from own practice	<input type="checkbox"/>	<input type="checkbox"/>

Reasons for using standardised extracts

8. Why do you use standardised extracts in your practice (please select all that apply and please give details if 'other' box selected)

Please select at least 1 answer(s).

- More effective
- Stronger
- Use for a specific action in the body
- Easier for patient to take
- Other

8a. If you selected Other, please specify:

Research training

9. Have you been trained in analysis of peer-reviewed research articles published in journals?

- Yes
- No
- Not sure

Research training

10. Was this on a formal training course or was it as part of CPD? If you select 'other' please give details

10a. If you selected Other, please specify:

10b. Have you found this training useful in your clinical practice?

Use of research

11. Approximately how often do you access peer reviewed research articles published in journals as part of your professional practice or ongoing CPD?

- Daily
- Weekly
- Monthly
- Yearly
- Never

Choice of product

12. Do you follow the result of these studies by using the standardised extract as specified in the studies or do you substitute the whole plant (or whole plant extract) for the same indications? If you have selected 'other' please explain

- I use the standardised extract similar to that in the studies
- I use the whole plant, despite the studies being on the standardised extract
- Other

12a. If you selected Other, please specify:

12b. For use of which plant medicine in your practice have you found modern research evidence most useful? Enter 'none' if applicable.

Clarity about choice of product

13. Are you unsure and lacking clarity about whether to choose a standardised extract or a whole plant medicine?

- Yes
- No
- Maybe

Clinical comparison of standardised extracts with whole plant extract

14. Have you ever directly compared a whole plant (or whole plant extract) to a standardised extract in your practice (e.g. whole turmeric to a 95% curcumin extract)

- Yes

No

Comparison trial

15. Which products did you compare? (give details of more than one plant if appropriate)

16. For each trial of comparison in your practice, which product/s did you find more useful?

17. Can you give any details of how it was more useful?

Side effects

18. Have you ever noted unwanted side effects from use of a standardised extract?

Yes

No

Not sure

Side effects

19. Please give details of the product and the unwanted side effect/s

19a. Did you submit a Yellow Card detailing the side-effects

Yes

No

Most likely clinical scenario for use of standardised extract

20. Can you think of the most likely situation where you would use a standardised extract, even if you haven't yet done so and it is purely theoretical?

Yes

No

Most likely clinical scenario for use of standardised extract

21. Please give the identity of the standardised extract

22. Please indicate why you would choose that product in the given situation or condition

Practitioner details

23. Approximately how many patients do you have contact with per week?

- 0
- 1-4
- 5-14
- 15-30
- 30+

24. Where did you undertake your training as an herbalist?

25. In which decade did you qualify as an herbalist?

26. What professional body are you a member of (please choose all that apply)

- CPP
- URHP
- AMH
- NIMH
- ANP

Final comments

27. Do you think it is useful to find out about UK herbalists' use of standardised extracts?

- Yes
- No
- Maybe

28. Do you have any further comments about use, or not, of standardised extracts in your herbal practice?

Request summary of study results

If you would like a summary of the results of this study, please send your email address to SSprung@UCLan.ac.uk and findings will be shared as soon as possible

Please note that once the 'finish' button is pressed, responses will be submitted and cannot be withdrawn

Thank you

Thank you for your time and effort, it is greatly appreciated and results will be disseminated as soon as possible.

Appendix 13: How the interviews and interview data informed the development of the survey

Findings from the interviews and themes identified were used to inform the development of the online survey, were wide ranging and are outlined below, and how questions specifically answer the survey aims. Findings outlined below concern current and past use of HSEs or WPEs and reasons and influences for choice.

It was difficult to find Interviewees who used HSEs. Interview data following the first general requests on social media represented only those herbalists who did not use HSE products in their practice, despite the recent 2015 data from the author's previous study (Sprung, 2016) which found over 40% of responding herbalists used HSE *C. longa* in practice. A central focus for the survey was therefore not only asking whether herbalists use any HSE in practice (Aim 2) (Question 2) and which HSE or HSEs they use (Question 6) but also asking whether they have used HSE in the past (Questions 4 and 5). It was anticipated that this data would help to clarify not only how widespread HSE use is but also how it may have changed over recent years (Aim 1)

In terms of influences and reasons for use of HSE or WPE (Aim 1), Questions 3, 7 and 8 addressed these questions, informed by specific interview data (summarised in a) -d) in Table 5.3 (p. 74) and discussed below). It was necessary for the questionnaire to focus on WPE use as well as HSE use because investigating HSE use will necessarily include issues involving WPE use. The influence of published research evidence on herbalists' practice is complex and interview data included many comments about this issue. Reference was made to perceived lack of useful research studies, limitations or lack of relevance of research applied to herbalists' clinical practice, quality of research, use of research when communicating with patients or doctors, using research primarily to confirm traditional use, limited time available for reviewing research, conflicting evidence from studies, inappropriate use of HSE research to justify the use of WPE. The questionnaire aimed to investigate the influence of research on practice with several general and more specific questions about research relating to these interview findings. Questions 9 and 10 aimed to find out whether herbalists reported being trained in research analysis, where they undertook this training and therefore whether they were likely to be using it in an informed way. Question 10b and 11 sought to find out how useful they have found this training and how often they reported accessing research studies. Question 12 asked about whether participants used HSE products when referring to research on those HSE herbs and also what specific herb research was found most useful. The open comments Question 28 also offered an opportunity to add any comments concerning research. The influence of direct clinical evidence from herbalists' own practice was found, with

practitioners having directly compared WPE to HSE in practice, with outcomes in favour of both preparations, albeit in different clinical situations. The survey therefore included questions investigating herbalists' own clinical evidence for informing choice of HSE or WPE, including any evidence of side effects, including yellow card reporting (for which there is little data) (Questions 14 to 19). A recurrent theme in interviews was influence from other experienced and respected herbalists and from herbalists on herbal training courses. Influential herbalists treating patients with cancer and other serious autoimmune and inflammatory conditions were reported to inform choice, via seminars and personal contact, to use HSE *C. longa* as well as WPE *C. longa* only. The questionnaire investigated influence of other herbalists in use of HSE (Question 7). Evidence from supplement company seminars about HSEs they sell were reported as lacking influence. 'Commercial interests' in HSE products and 'ethics' of those companies were reported as a factor in not using HSEs and the questionnaire asked whether information from HSE manufacturers was influential or not (Question 7). Reasons for using HSE included requirement for large doses of herbs, a quick or strong result or specific use, as well as more practical reasons. Question 7 asked for reasons for using HSEs and this was further investigated by asking for an example of when a HSE would specifically be used in practice and reason why (Questions 20 to 22). Herbalists who did not use HSEs reported 'non-scientific' reasons for choice of preparation, based on a preference for the natural WPE. Question 3 sought to find out more about this issue; being open text it aimed to provide a large amount of data concerning reasons for not using HSEs. There were also reports of finding the issue of HSE compared to WPE complex, unclear and controversial and that more information about herbal practice would be very 'useful' and 'interesting'. A repeated example of how herbalists may be unclear is the phrase 'have a feeling' regarding preferential use of WPE and using WPE alongside HSE. The survey asked about clarity (Question 13) and how useful the participants think this research question is (Question 27). From the interview data there is no evidence that any herbalists disagreed with the use of HSE products by those who find them beneficial, suggesting that they were open-minded about HSE use. Additionally there were overt statements amongst 2 of those who did not use HSEs, indicating that they were open minded about HSE use in their practice if they felt it was necessary. To test the extent to which herbalists are indeed open-minded about HSE use, the questionnaire included a question asking whether they could imagine using an HSE in practice, even if they did not use HSEs at that time (Question 20) and if so, details were requested of the specific HSE and reasons for use (Questions 21 and 22). Linked to the themes of direct clinical evidence and influence of respected herbalists, another theme that emerged is of herbalists having used HSE in the past but no longer using, and Questions 4 and 5 asked about this. Other factors that varied between Interviewees that may influence HSE use include busyness of

practice, experience, training history, date of qualification and PA membership. Demographic questions were included in the survey (Questions 23 to 26).

Appendix 14: charts and diagrams to represent answers to questionnaire

Q3: Table showing reasons given for not using HSE

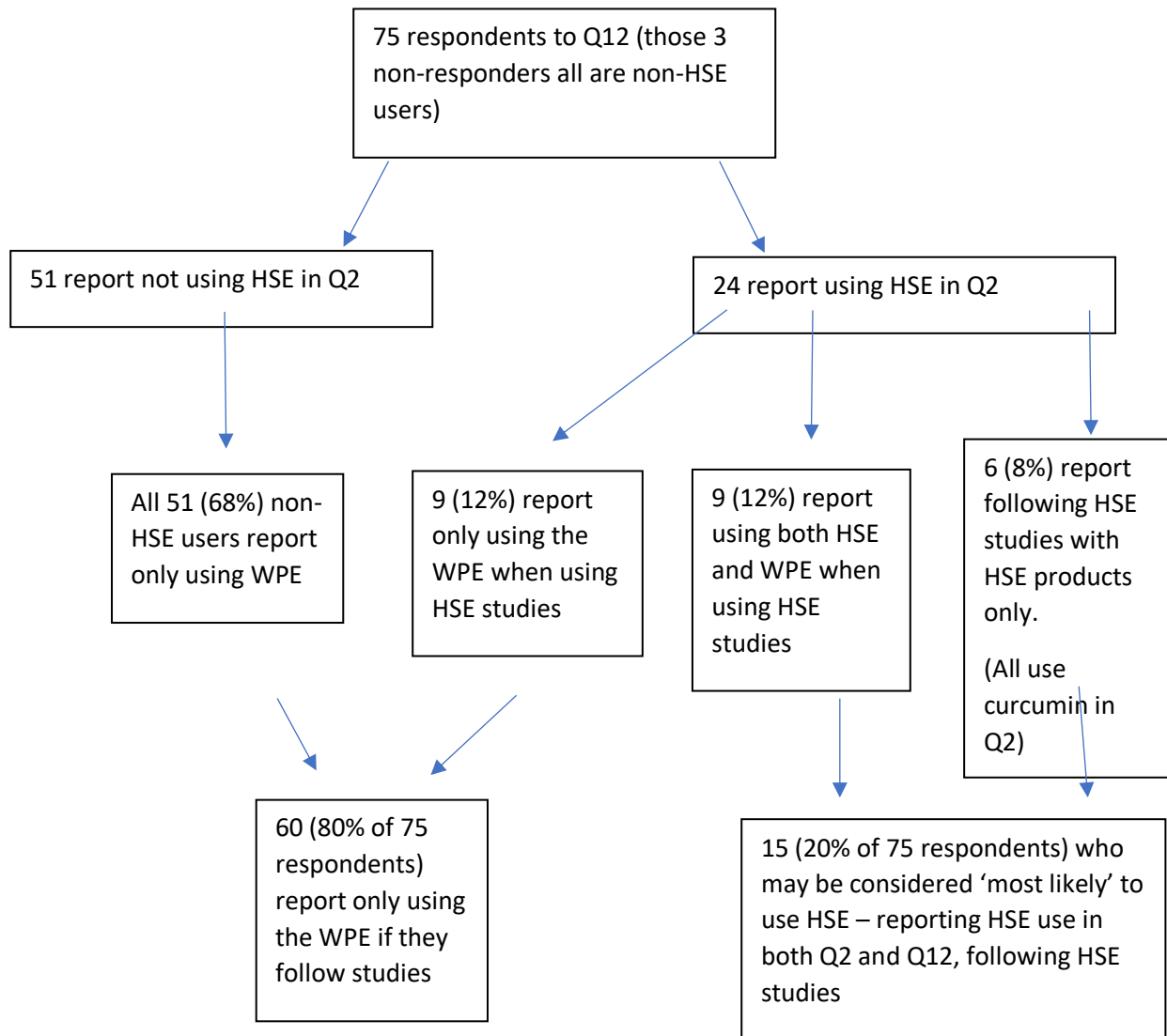
<p>I would rather use whole plant extracts in their natural strengths. I am not convinced that by 'supercharging' certain constituents it gives any greater advantage. It may be that the full chemical balance that occurs naturally, that is the full range of constituents represents the optimum way of presenting these chemicals for best use by the body. I can't help thinking that standardised extracts are a way of marketing and making more money from natural medical products. I have had patients who have used standardised extracts (although not prescribed by me) who don't seem to have experienced any miraculous effects from their use.</p>
<p>It is my belief that it is virtually impossible to know without doubt which constituent has a given effect, and furthermore, that that effect may well not occur if the balance of constituents is altered. This, in my opinion, then turns the plant, and the way it has been used safely for generations, into a pseudo drug, potentially with adverse effects. We inherit a wealth of historic information from our predecessors regarding use of whole herbs. I prefer to use this tried and tested approach, even if, perhaps, this approach takes longer to achieve effect.</p>
<p>Small practice, limit range of products used</p>
<p>It works on the assumption that nature knows best. That it has balanced the constituents is a safe and effective way. I believe the constituents work synergistically and isolating one aspect, is moving more towards orthodox medicine and away from the holistic principles of herbal medicine.</p>
<p>the patients aren't standardised</p>
<p>I prefer to use the whole plant extract</p>
<p>I am concerned that in extracting one active principle I may finish with a tincture that lacks some vital aspect of the plant. We need more research to justify standardised extracts. It's also not clear if SEs are legal under the terms of the 1968 Medicines Act.</p>
<p>These products are standardised on just one component. Other constituents can vary wildly if only one component is considered. In addition, herbal medicine is about using products as close to natural as possible.</p>
<p>Prefer whole herb as nature intended</p>
<p>The phytochemistry of herbs is complex and except in the case of powerful herbal medicines such as "schedule 3" type herbs which often have a more dominant phytochemical e.g. tropane alkaloids I suspect that anchoring a herbal extract on one particular phytochemical overlooks the overall synthesis of the plant's phytochemistry.</p>
<p>I was taught to use whole herb extracts, and I find that whole herb extracts have a good therapeutic clinical effect, and I would not like to use a herb based on one single extract, it does not match my view of plant medicine</p>

I believe in the benefits using the whole herb can bestow.
I TEND TO USE SIMPLES, TEAS, TINCTURES, FLUID EXTRACTS, CAPSULES. THIS IS how I was trained. I am aware that the standardised extracts are more potent. This is very expensive and needs a lot of space to comment fully.
I don't really have strong views on them but I use tinctures and powders, I don't like to stock expensive standardised extracts but don't discourage clients from purchasing them if they enquire.
I prefer whole herb preparations
I prefer to use plant extracts as they come naturally from plants. we really don't know that one particular chemical should be in a higher concentration than it is in nature. There may be many reasons for a reduced amount of a particular chemical in a plant and we assume more knowledge than we actually have if we say that we need a certain strength for example
I prefer to use tinctures, fluid extracts and dried herbs/powders.
Cost and the fact that I am looking for a more rounded approach generally. Also, haven't yet found a need to use them.
I am happy with the results from the products I use.
It seems to me that there are benefits to many compounds within each medicinal plant, not only the compounds so far studied. It is not clear what effect standardised extracts have on synergy. I am less interested in the idea of finding linear effects through monochemicals, hence my interest in practising as a herbalist rather than as a doctor.
The whole plant is more effective, probably because of synergistic effects of several components
Lack of long term safety data & unknown buffering/mediating benefits of 'crude' plant matter
I am concerned that the chemical balance of a plant may be so changed that important constituents are no longer bio-available. We don't know enough about this and more research needs to be undertaken to validate use of these new products. It's also open to question whether or not these extracts are legal under the 1968 medicines act.
I prefer whole herb extracts
I prefer the whole plant extract.
I do not use plants as weak pharmaceuticals in any case so using them as standardised pharmaceuticals makes no sense
I believe that standardisation (as understood in this questionnaire) distorts the natural ratio of the plant's constituents.
My preferred suppliers do not offer them
It feels wrong like they are modified in some way and herbalism to me needs the original plant for the synergy of the medicine.
I prefer to use the whole plant as believe there is a synergistic effect from the individual components working together

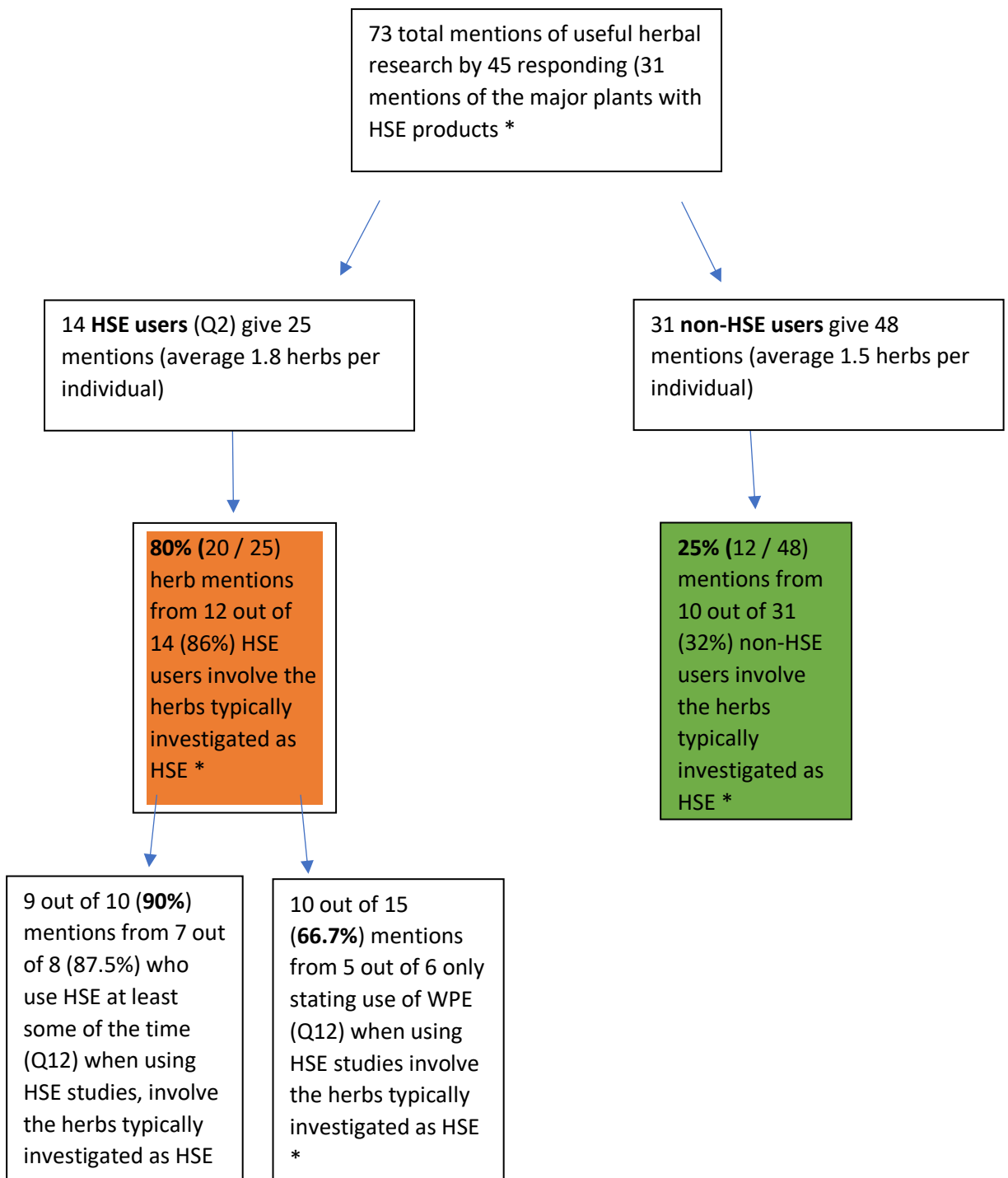
<p>Because I more often see side effects with them when I used to use them. One standard constituent doesn't constitute the whole story with 'activity' of a herb.</p>
<p>I have in the past, just not required for my patients currently</p>
<p>A plants effect is greater than a standardised extract - it is not possible to standardise herbs on one standardised substance. When hypericum was standardised to hypericin it still worked when the hypericin was removed - so why standardise it to a random plant product? so I am against this pseudo science reductionist approach- plants are more than standardised extracts if you want to use standardised extracts then train to be an MD and use drugs</p>
<p>I generally prefer the concept of the full plant and its spectrum of constituents in their original/organically acquired balance</p>
<p>Prefer whole plant - --not convinced by supposed effects of extracts, often research not done on humans.</p>
<p>I feel it is unnecessary and that other plant constituents are also important. I'm not aware of any research that compares standardised and non-standardised plant extracts but would be interested in this, otherwise it seems a bit like a marketing ploy. I'm happy to accept some level of variability in herbs. I can understand difficulties with e.g. bioavailability of curcumin in turmeric in which case it might be warranted to standardise it and I would potentially recommend it to clients but would be unlikely to dispense them directly from myself. It's partly a practical thing too - since I almost exclusively use tinctures, these are very rarely standardised.</p>
<p>I believe the whole natural plant works better and all its constituents in synergy with each other in ways we may not yet understand</p>
<p>Difficult to explain. I try to use as natural as possible, recommend using herbs in food, and think we should be using the plants as they are, not added to or taken away. I am not convinced that one constituent is responsible for all the therapeutic benefits of a plant and I wonder what happens long term when you start using standardised extracts weighted for this action or that action. That's not how they evolved in traditional use. Look at cannabis. They've engineered higher THC plants for recreational use, reducing the more therapeutic cannabinoid content and started seeing mental health repercussions.</p>
<p>I prefer to use whole plant with all of its constituents as they are</p>
<p>I believe in using the whole plant as it comes in nature. Also, they are more expensive.</p>
<p>more expensive and I don't believe the constituents in a plant should be tampered with.</p>
<p>A belief that the whole is greater than the sum of the parts and that by standardising to one component you may be losing out on something else that is crucial to the balance and action of the herb.</p>
<p>Not natural plant balance of constituents</p>
<p>I believe that when we "meddle" with the plant we have a higher risk of side effects and don't believe this is true herbal medicine.</p>
<p>I have had bad experiences of standardised products in the past</p>

<p>I have never felt the need and when tempted am reminded of other herbalists using plants traditionally to good effect. However I have spent 1/2ay a week working in a health shop and have recommended standardised extracts as part of an OTC approach when individualised prescribing hasn't been appropriate.</p>
<p>I do not agree with the synthetic addition of constituents to a plant based product. Natural variability is part of the deal when using herbal tinctures. We learn to work with this.</p>
<p>Prefer to use the whole plant part just as it is. I trust the plant to know best. There are always useful elements in a whole plant other than those which are deemed to be the "active" ingredient.</p>
<p>Habit? I actually take standardised <i>G. biloba</i> tablets myself as want to have the recommended dose.</p>
<p>I prefer a whole extract , with all constituents as they are .</p>
<p>I do not feel it is necessary or desired. I prefer whole fresh plant tinctures</p>
<p>The products have been chemically manipulated to have a guaranteed amount of specific chemical constituents and does not fall in line with whole plant extract as Nature intended.</p>
<p>Plants are a synergistic combination of many thousands of constituents, a lot of which we have no clear understanding of. Disrupting this synergy for individual constituents doesn't make sense to me as an herbalist.</p>

Q12a Diagram showing how herbalists choose products after using HSE research studies



Q12b: Diagram showing stated useful herbal research in terms of HSE use and non-HSE use (Q2 and 12)



* The plants with widely available HSE products used - –*C. longa*, *G. biloba*, *S. marianum*, *S. palmetto*, *B. serrata*.

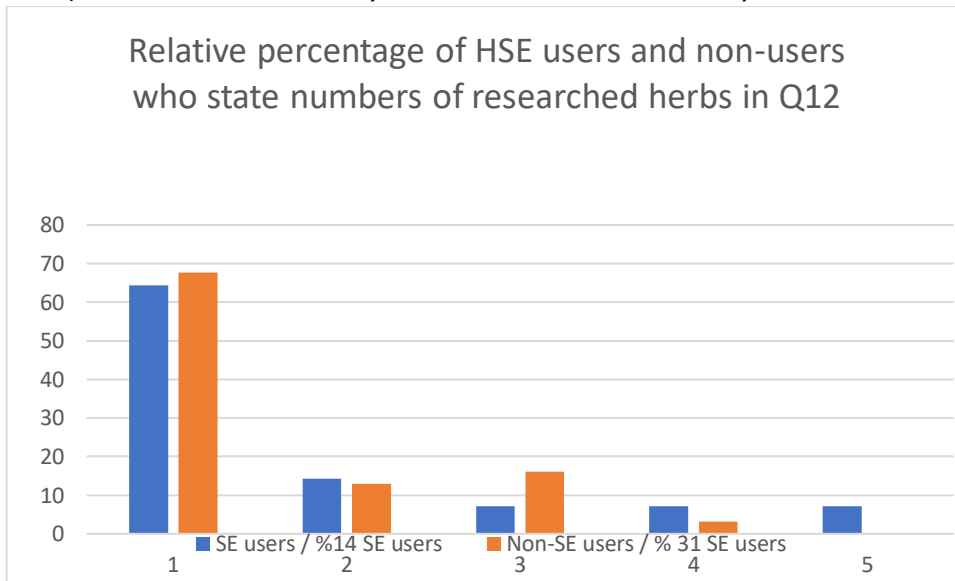
Q12b) Table to show how frequently herbs are mentioned as most useful research by HSE users and non-users

26 herbs in total	Number of mentions / % of total 73 mentions	% of 45 responding mentioning herb	Mentions by 14 HSE users (Q2) / % of 14 HSE users	Mentions by 31 non-HSE users (Q2) / % of 31 non-HSE users
<i>C. longa</i> *	18 / 25%	40%	10 / 71%	8 / 26%
<i>Echinacea spp.</i>	8 / 11%	17%	2 / 14%	6 / 19%
<i>G. biloba</i> *	7 / 9%	15%	3 / 21%	4 / 13%
<i>Hypericum perforatum</i>	6 / 8%	13%	1 / 7%	5 / 16%
<i>S. marianum</i> *	4 / 5%	11%	4 / 29%	0
<i>Glycyrrhiza glabra</i>	3		1	2
<i>Sambucus nigra</i>	2			2
<i>Berberis vulgaris</i>	2			2
<i>Thymus officinalis</i>	2			2
<i>Cimicifuga racemosa</i>	2			2
<i>Melissa officinalis</i>	2			2
<i>Rhodiola rosea</i>	2			2
<i>Vitex agnus castus</i>	2			2
<i>S. serrulata</i> *	1		1	0
<i>Boswellia serrata</i> *	1		1	0
<i>Paeonia lactiflora</i>	1		1	0
<i>Withania somnifera</i>	1			1
<i>Coriolus/cordyceps</i>	1			1
<i>Urtica dioica</i>	1			1
<i>Rosmarinus officinalis</i>	1			1
<i>Capsicum minimum</i>	1			1

<i>Pelargonium spp.</i>	1		1	0
<i>Ballotta nigra</i>	1			1
<i>Centella asiatica</i>	1			1
<i>Eleutherococcus senticosus</i>	1			1
<i>Symphytum officinalis</i>	1			1

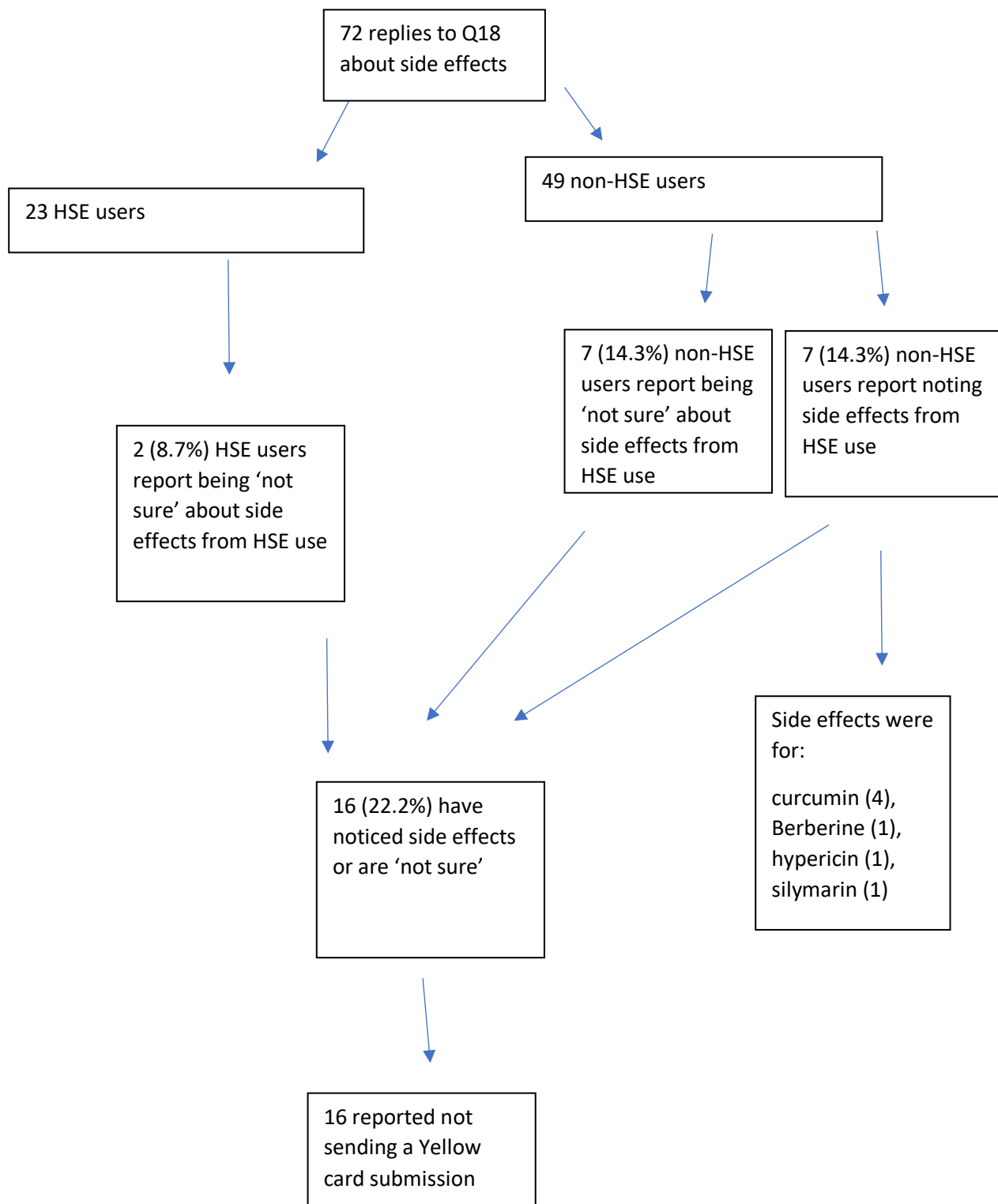
* Herbs widely available as HSE products, 30 mentions; WPE – 43 mentions

Q12b) Chart to show how many researched herbs are stated by RH:

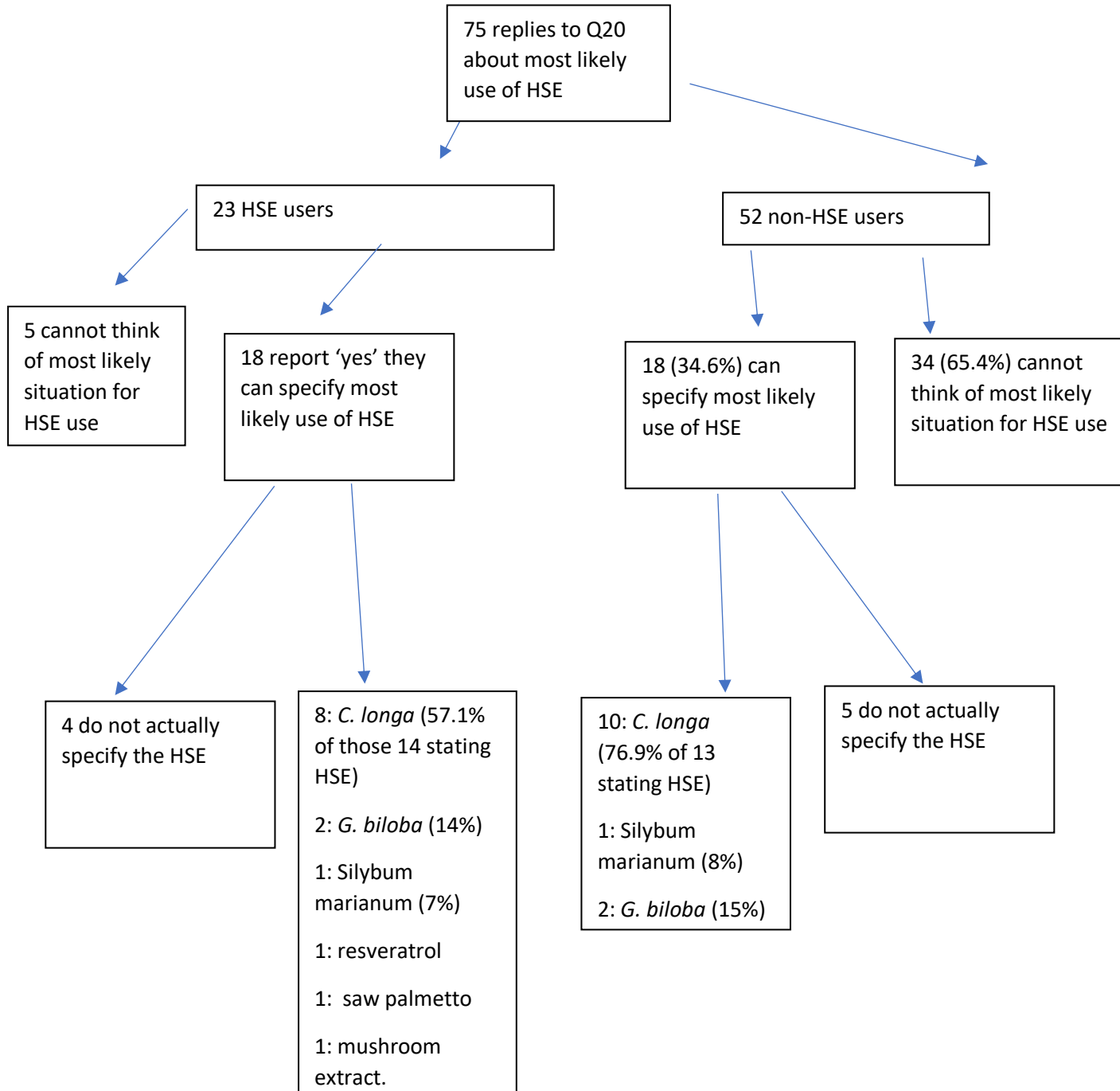


Q. 18-19: Have you ever noted unwanted side effects from use of a standardised extract? Please give details of the product and the unwanted side effect/s. Did you submit a Yellow Card detailing the side-effects?

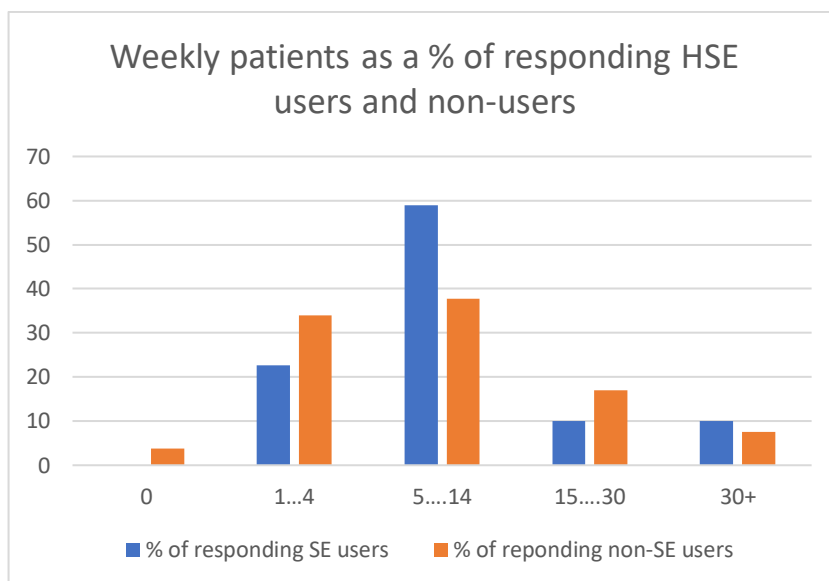
Diagram showing reports of side effects from HSE use as reported by HSE users and non-HSE users



Q20-21: Can you think of the most likely situation where you would use a standardised extract, even if you haven't yet done so and it is purely theoretical? Please give the identity of the standardised extract.



Q23: Approximately how many patients do you have contact with per week?



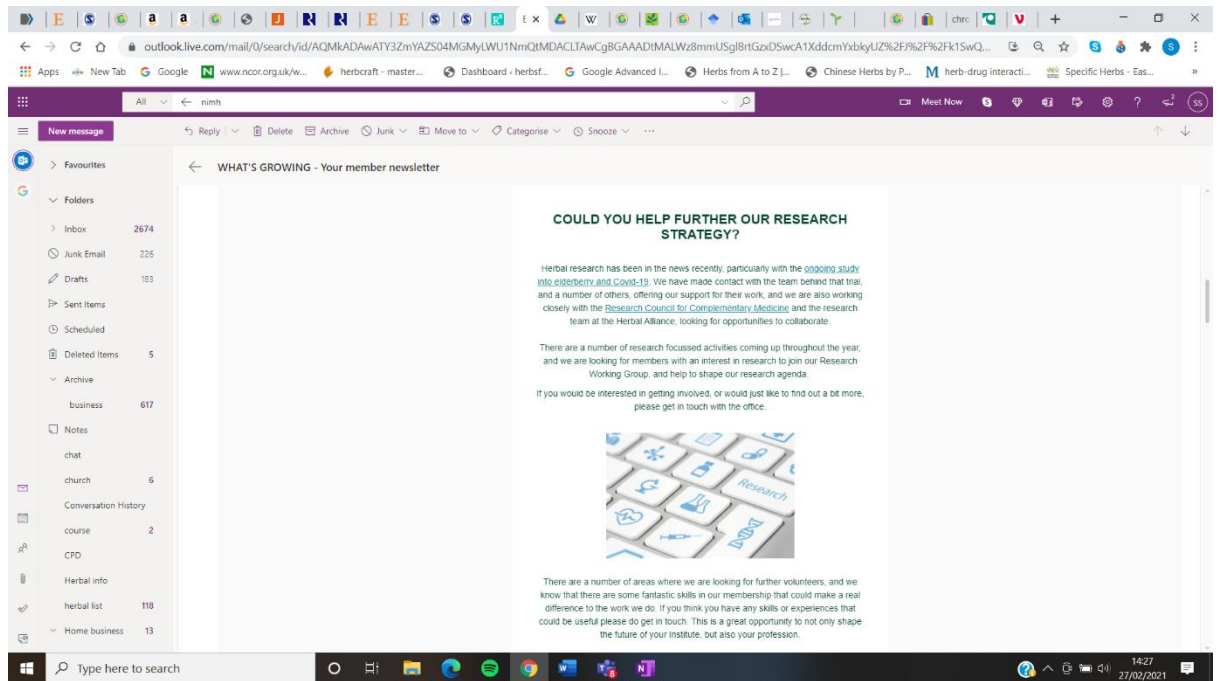
Q 25: In which decade did you qualify as an herbalist?

Decade qualified	70s	80s	90s	00s	10s
% of 23 HSE users from decade	0	1 / 5%	3 / 14%	10 / 45%	8 / 36%
% of 51 non-HSE users from decade	4 / 8%	5 / 10%	5 / 10%	21 / 41%	16 / 31%

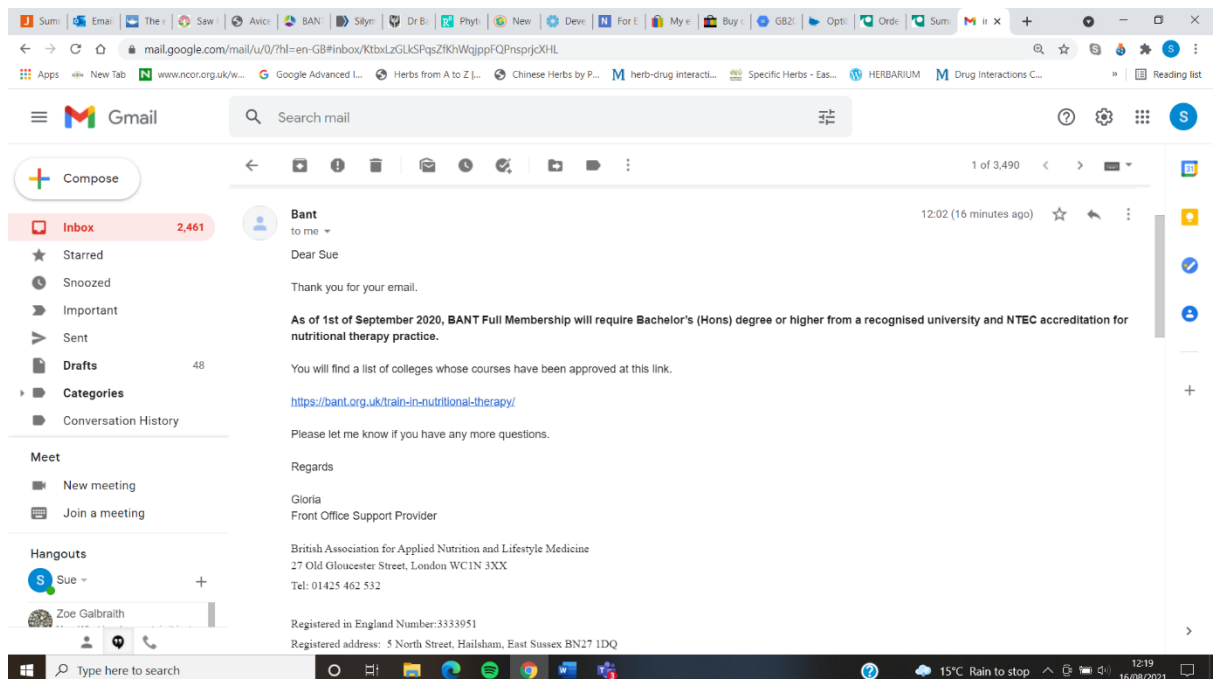
Q27: Do you think it is useful to find out about UK herbalists' use of standardised extracts?

	Useful	Maybe	Not useful
Number / % out of 76 responses	52 / 68%	21 / 28%	3 / 4%
Number who use HSE / % of those 24 using SE	16 / 67%	7 / 29%	1 / 4%
Number not using HSE / % of those 52 not using HSE	36 / 69%	14 / 27%	2 / 4%

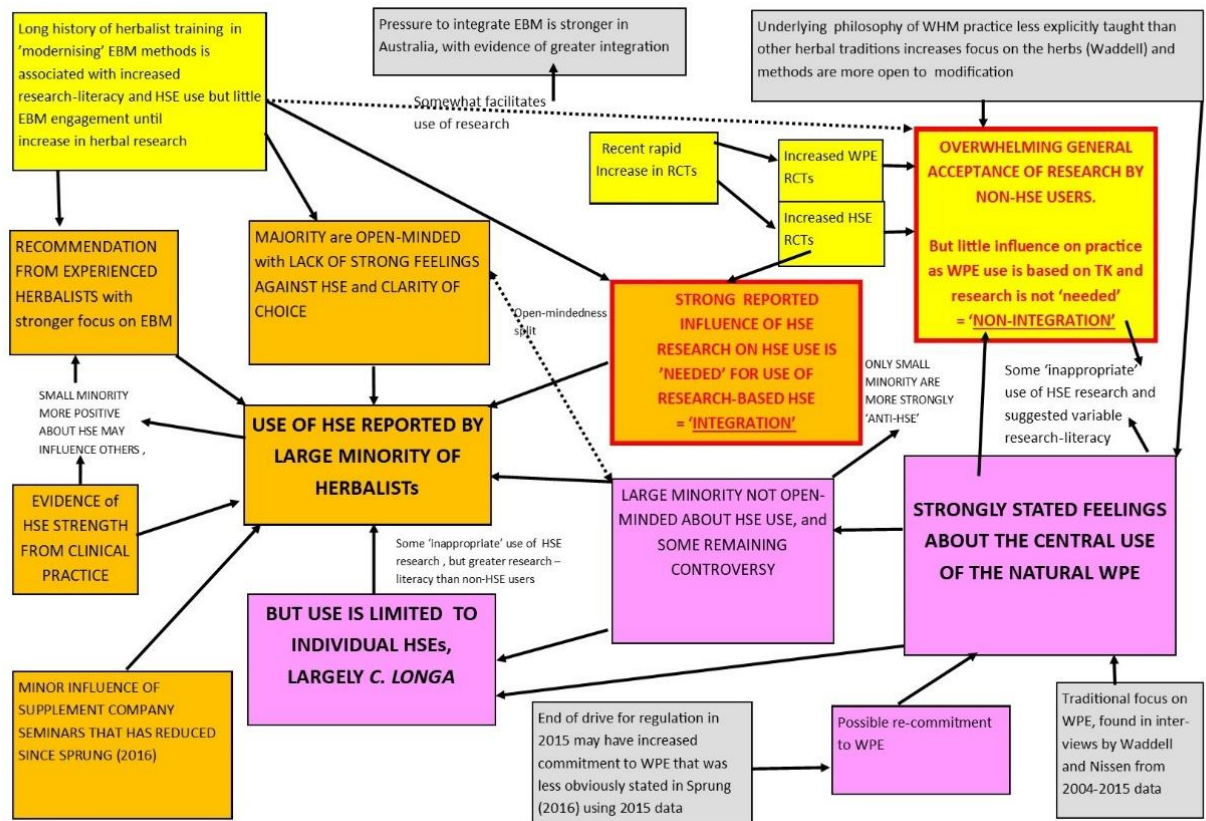
Appendix 15: NIMH newsletter asking for collaboration in research projects from members



Appendix 16: BANT email



Appendix 17: Flow chart to show major theory about HSE use developed in the study



Key for Figure 7.1

