RESEARCH PROPOSAL
Reversing Type 2 Diabetes

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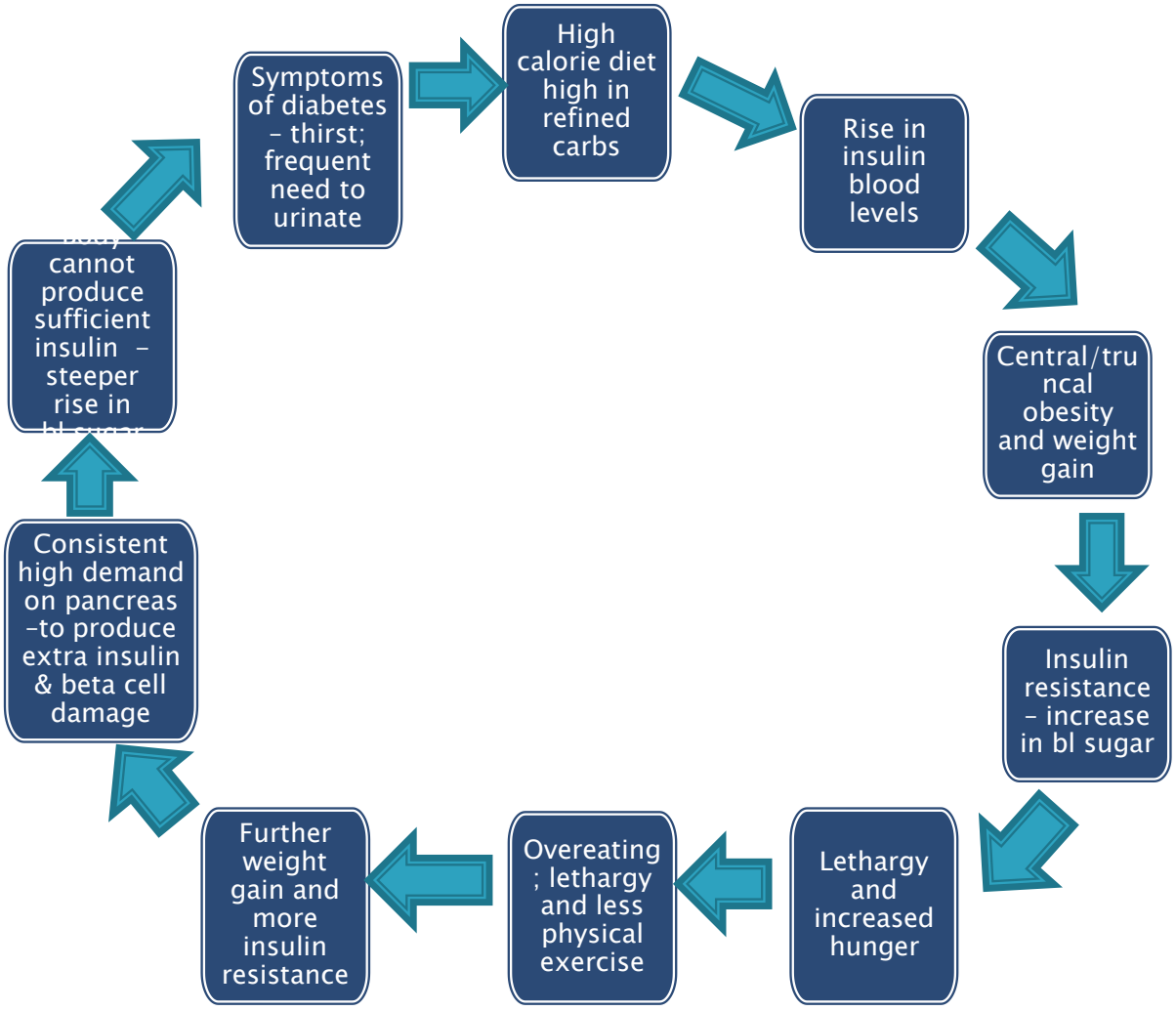
Reversing Type 2 Diabetes

- Long-term improvement in insulin sensitivity in people with type 2 diabetes.
- HbA1c below 42 mmol/mol (6%) without taking diabetes medication are said to have reversed or resolved their diabetes – remission.
- Loss of body weight can be particularly beneficial in helping to reverse the progression of diabetes. The most common cause of type 2 diabetes is obesity-related, which generally follows a vicious cycle pattern.

Breaking the Cycle of Type 2 Diabetes



Low Carbohydrate Diets

KEY MESSAGES FROM PUBLISHED EVIDENCE

- Low-carbohydrate diets are known for **lowering the amount of insulin** the body needs to produce, resulting in **less insulin resistance**.
- A study published in 2014 by the Second University of Naples showed that a **low-carbohydrate** Mediterranean diet was able to achieve **significant rates of remission in people with type 2 diabetes**. After one year of following the diet, 15% of participants achieved remission and, after six years, 5% had achieved remission on the diet.
- By comparison, low-fat diets were not as effective in the study. After one year, 4% of participants on a low-fat diet had achieved remission and, after six years, 0% of participants had achieved remission.
- Dr David Unwin, a UK GP, has run studies that have demonstrated reversal of diabetes in a number of his after following a reduced-carbohydrate diet.

Very Low Carbohydrate Diets

- Very low carbohydrate diets (VLCD) have been shown to achieve **significant weight loss, reduce insulin resistance** and allow people with type 2 diabetes to **come off their diabetes medication**.

- In 2011, a study was published by researchers at Newcastle University showing that an **8-week 800 kcal per day diet** was able to achieve **remission from diabetes in seven of the 11 participants** that took part. The trial used MRI scans and showed that the reversal of diabetes appeared to be correlated with significant reductions in fat storage within the liver and pancreas.

- Currently, **Newcastle University** are running a study **involving 32 participants.** The participants were put on a similar diet for a similar length of time and then followed a low calorie weight maintenance diet.

- The participants will be **reviewed for at least two years** to see **how many of the participants can maintain diabetes remission** over this period. Initial results show that 40% of participants had achieved and maintained remission from type 2 diabetes six months after

Exercise

- Commitment to exercise has allowed a number of people to successfully reverse their type 2 diabetes.
- Exercise helps the body to become **more sensitive to its insulin.** In combination with a healthy diet, exercise can reduce the demand for insulin in the body and therefore help reverse diabetes.
- The people that have used exercise to **reverse their diabetes** have done so by **combining exercise with healthy eating.** There have been a number of anecdotal accounts showing exercise to be linked with diabetes remission.
- A study published in 2015 showed that **67% of participants were able to achieve partial remission** of their type 2 diabetes having taken part in a **six-month diet and exercise program.** The participants in this study were newly diagnosed with type 2 diabetes.

Local Findings

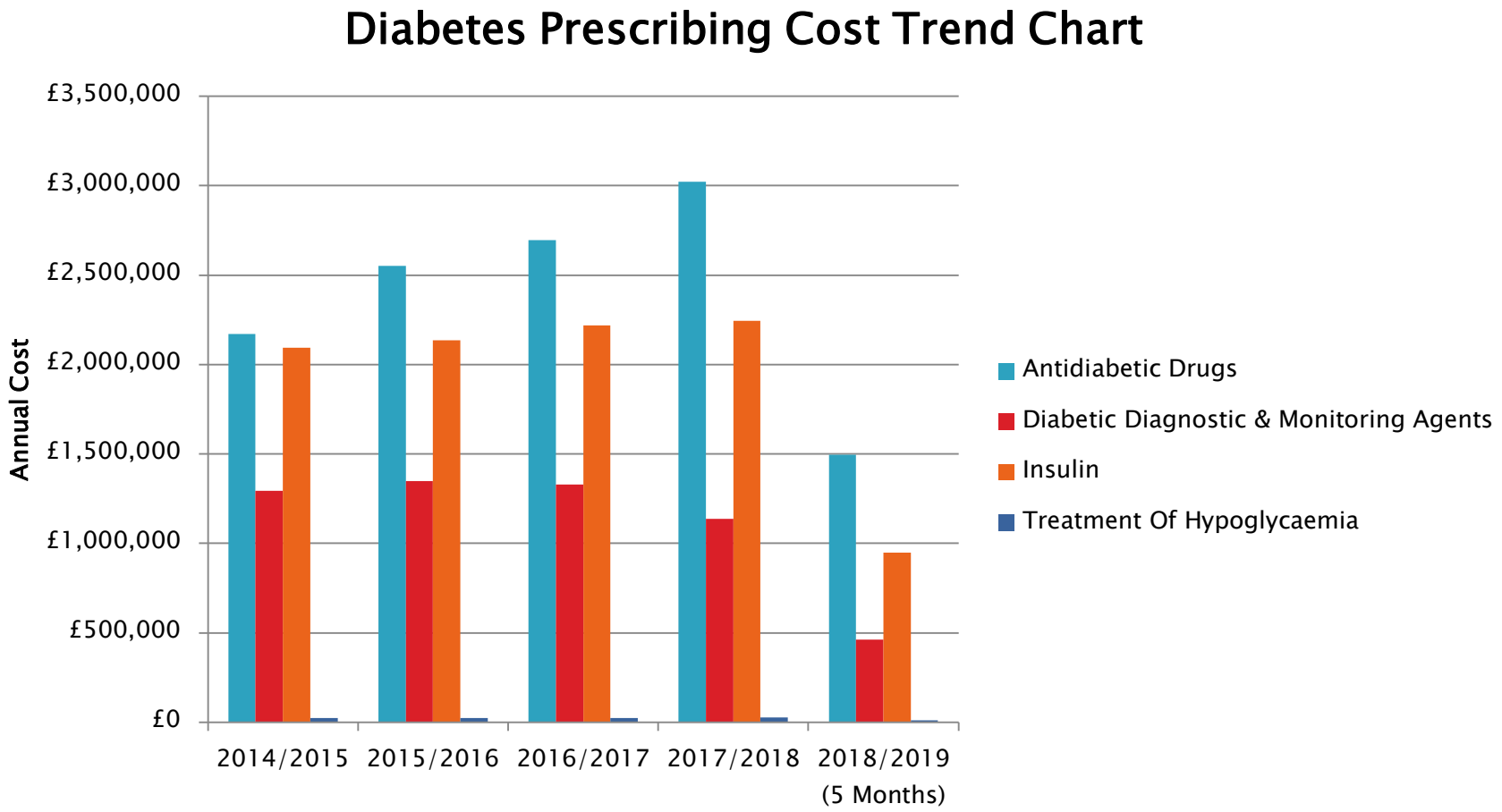
- A small pilot from a practice in a neighbouring CCG **recruited 30 patients** with Type 2 Diabetes on a **Modified Mediterranean Diet** and after **3 months** results showed average of **7kg weight reduction** and **16mmol HbA1c reduction** per patient, plus patients **came off their anti-diabetic medications.**

- This reflects the findings from Dr Unwin's practice (9,600 patient list) which saved **£38K in 12 months** on **anti-diabetic drugs.** This should also lead to a reduction in admissions/referrals due to better control of diabetes, BP, cholesterol etc.

Local Diabetes Prescribing Trends

Costs	2014/2015	2015/2016	2016/2017	2017/2018	2018/2019 (5 Months)
Antidiabetic Drugs	£2,170,599	£2,550,419	£2,694,090	£3,020,543	£1,494,229
Diabetic Diagnostic & Monitoring Agents	£1,294,812	£1,347,956	£1,328,907	£1,136,071	£460,811
Insulin	£2,092,190	£2,133,860	£2,219,294	£2,243,335	£947,394
Treatment Of Hypoglycaemia	£24,015	£22,709	£24,230	£25,162	£9,823
Grand Total	£5,581,616	£6,054,945	£6,266,520	£6,425,110	£2,912,258
Items	**2014/2015**	**2015/2016**	**2016/2017**	**2017/2018**	**2018/2019 (5 Months)**
Antidiabetic Drugs	244919	256170	269039	278205	121727
Diabetic Diagnostic & Monitoring Agents	56707	56253	54724	52182	22032
Insulin	52547	53470	54913	55293	23686
Treatment Of Hypoglycaemia	1837	1837	1842	2032	843
Grand Total	356010	367730	380518	387712	168288
Cost/item	**2014/2015**	**2015/2016**	**2016/2017**	**2017/2018**	**2018/2019 (5 Months)**
Antidiabetic Drugs	£8.86	£9.96	£10.01	£10.86	£12.28
Diabetic Diagnostic & Monitoring Agents	£22.83	£23.96	£24.28	£21.77	£20.92
Insulin	£39.82	£39.91	£40.41	£40.57	£40.00
Treatment Of Hypoglycaemia	£13.07	£12.36	£13.15	£12.38	£11.65
Grand Total	£15.68	£16.47	£16.47	£16.57	£17.31

Local Diabetes Prescribing Trend



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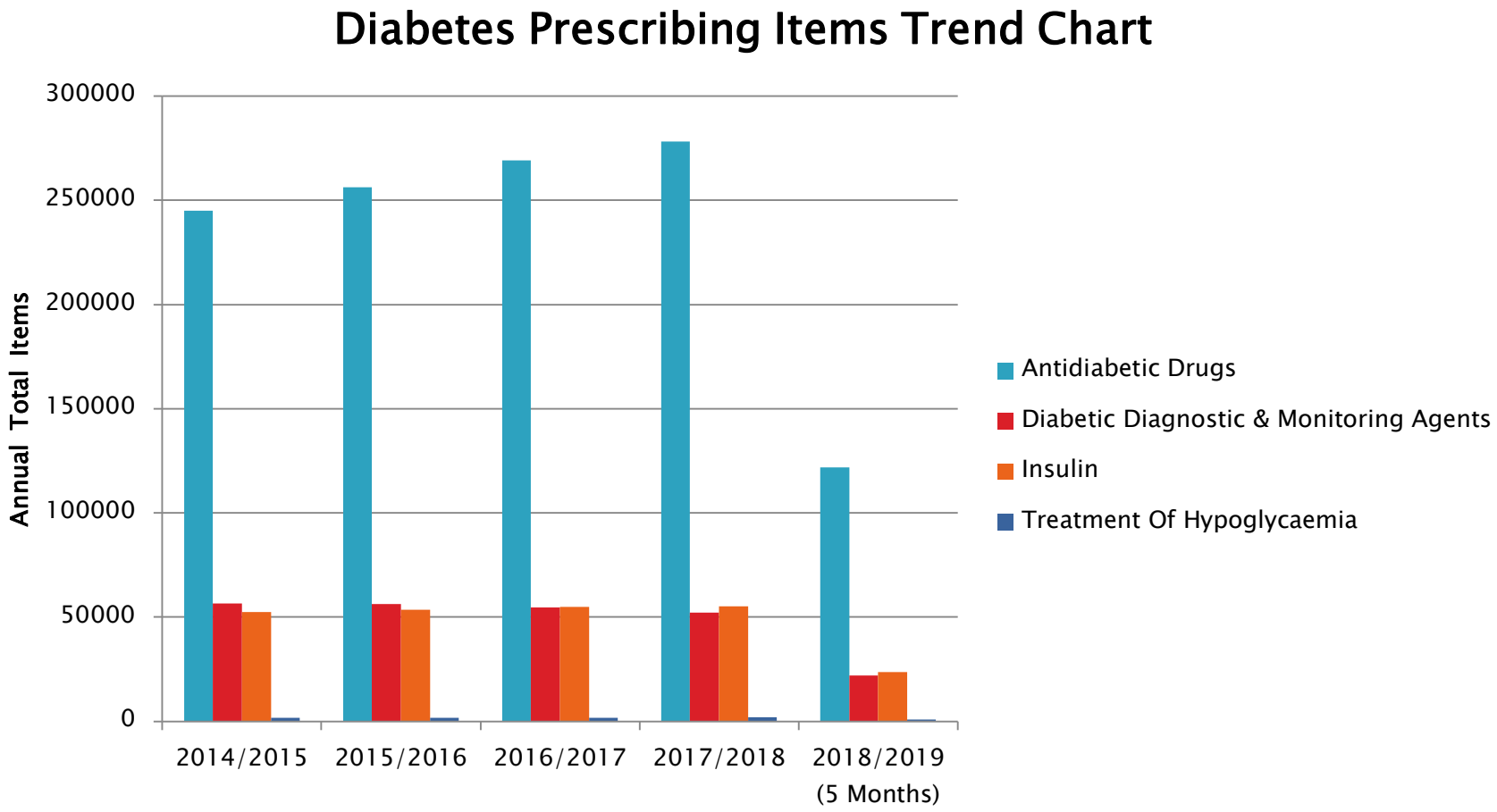

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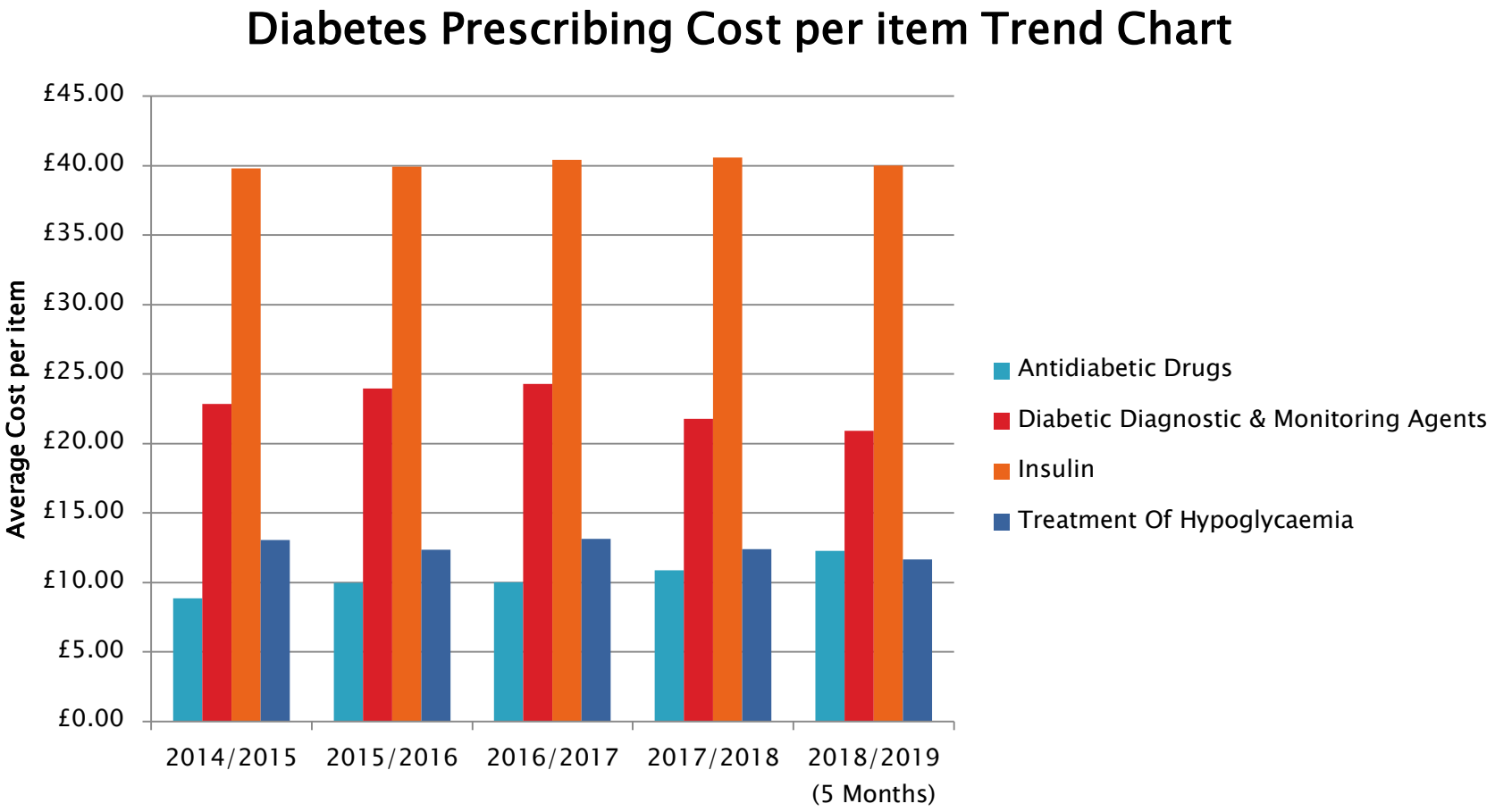

Research Proposal/Evaluation

- To recruit patients with Type 2 diabetes registered with GP practices in primary care to participate in a qualitative study using reduced calorie/low carbohydrate diets over a period of 6-12 months with weekly/monthly/quarterly follow ups to establish progress and offer support, mentorship and advice where required.

Proposed Monitoring

Patients will be monitored at regular intervals against the following criteria:

- Weight Loss – Bi-weekly
- Support and mentorship – 1-2 weekly
- BP – Bi-weekly
- Cholesterol – monthly
- HbA1c – quarterly
- Medication review – quarterly

Potential Outcomes

- % change in weight from baseline
- % BP change from baseline
- % change in cholesterol from baseline
- % change in HbA1c from baseline
- Changes in medication from baseline
- Qualitative analysis on support and mentorship required

Findings

- A longitudinal analysis will capture not only the quantitative % changes in clinical markers but also the qualitative impact on individual patients in terms of their personal experiences, challenges and goal-setting.
- The latter aspect is crucial given this is a key driver for achieving the clinical outcomes.

Implications

- The model could be scaled up across practices/organisations depending on outcomes.
- The model can be adopted to suit different populations that enable alternative methods to be carried out. This may include comparisons to explore interventions that work for minority ethnic groups; social deprivation and/or rural isolation to ensure the wider determinants of health are captured.
- Involvement of multi-disciplinary teams including patients is essential.
- This may require additional investment initially but this could be offset with additional costs of unnecessary drugs and/or hospital admissions/referrals. This aspect may require statistical modelling given the numbers recruited are likely to be relatively small.

Questions