COURSEWORK

24th April 2024

Reviewing A Methods Section

Practical: Reviewing a Methods Section

Task

Read through this research plan with a critical eye. Does the methods section, as presented, convince you that:

- The researchers will be able to answer the research question?
- That the methods being used are appropriate & scientifically rigorous?
- That the proposed work is feasible?

What could be improved, e.g. in terms of structure, detail, presentation?
Is the methods section complete?
Is the methods section clear?

The plain English summary and aims are included for background information.

Plain English Summary: Weight loss surgery works by helping to reduce the number of calories in the body by either reducing the size of the stomach or by bypassing the small intestine. Studies have shown that such surgery leads to sustained weight loss over a long period of time. Surgery does, however, carry some mainly short term risks. In some patients with late onset (type 2) diabetes, surgery has cured their diabetes. However, surgery is normally only done on severely obese patients i.e. with a Body Mass Index greater than 40. Those with a lower BMI of less than 35 and diabetes must try other methods to reduce their weight. These methods have shown very limited effectiveness, particularly over the long term. More research is needed in order to understand the role surgery might play for those with diabetes who are not so severely obese. In order for such research to succeed it is crucial that we understand patients' willingness to participate in such a study and identify potential barriers to taking part. This study assesses the attitudes of patients with type 2 (or late onset) diabetes to having surgery to improve their weight and better manage or lead to resolution of their diabetes. The views of clinicians will also be sought and will help to identify whether they feel weight loss surgery is appropriate for this group of patients and if so, what type of surgery would be suitable for particular patient characteristics (e.g. age, BMI). If patients and clinicians do feel that surgery would be an appropriate part of their weight and diabetes management, then this research will show whether it is feasible to run a trial to compare weight loss surgery with non-surgical alternatives in such patients. We also aim to identify a patient advisory group to assist with the further development of the trial design and materials. *(Taken from the RfPB website)*

Aims

i) To explore the attitudes and beliefs of patients with type 2 diabetes and non-morbid obesity (BMI 30-40kg/m2), about the role of bariatric surgery and other weight loss interventions in their management. To ascertain whether they would consider entry to an RCT which randomised to BS.

ii) To identify the number of patients with BMI 30-40 kg/m2 and type 2 diabetes who might be potentially eligible for an RCT in a sample of GP diabetes registers in the South West (SW) and the Central England (CE) PCRNs.

iii) To assess the attitudes of bariatric surgeons, GPs, and diabetologists to BS as a treatment option for such patients; their opinions on participating in an RCT above and for which sub-groups of patients (e.g. HBA1c level), and their equipoise over gastric bypass and banding. *(Taken from the RfPB website)*

Optimum care for non-morbidly obese patients with type 2 diabetes: the perspectives of patients and clinicians on the role of bariatric surgery. (Roderick et al., 2010; edited to make points)

GP practices who are members of the ***** and England PCRNs will be contacted and asked to see if they would be willing to participate in the study. Of those that reply positively, 40 practices will be selected to provide a variety of rural/urban, socio-economic and where possible, ethnic mix. (We recognise that such GPs may not be representative of all GPs but they would be likely recruitment sites for an RCT and their patients will be equally representative).

The Diabetic Lead GPs in these 40 practices will be asked to co-ordinate:

1.1 Database Search: A pro-forma will be developed to aid identification of the number of Type 2 diabetics with BMI 30-40 kg/m2 aged 18-74 with no obvious contraindications to BS (i.e. secondary diabetes, previous BS, drug/alcohol addiction, mental health problems, recent major CVD, recent /malignancy (though not non melanotic skin), advanced or severe CKD, liver fibrosis /portal hypertension, severe respiratory disease).

(We will sample patients with BMI 27.5-40 kg/m2 in south Asian patients, 27.5 is the WHO 's lower public health action point for south Asian patients who have more body fat than Caucasians at the same BMI level.) Clinical details (year of diagnosis, latest HbA1c, Framingham risk score if available and age) will allow calculation of the effect of various cut points on potential sample size. Details of the ethnic mix and the Index of Multiple Deprivation of their catchment area will be obtained if available (or derived for the practice's Local authority using the practice postcode and Geo-convert system).

Preliminary work in one practice (***) revealed 220 registered patients with diabetes (2.8% of list) of whom 124 (56%) had a BMI>30. Of these 47 were aged below 65 and had a BMI in the 30-40 range. A further 7 were excluded due to medical contraindications or prior surgery leaving a potential sample of 40. However this would be reduced further if duration or diabetes control were restrictive entry criteria and we do not know how many would then be willing to accept surgery and entry to a randomised trial. Such data will be crucial in trial planning.

1.2 Qualitative Interviews:

Sampling:

In 5 practices from different demographic areas, a purposive sample (based on BMI, age, gender, ethnic and socioeconomic factors) of 60 patients (ie 12 per site) will be invited by their GP to participate in the qualitative interview study. From respondents, 30 patients will be selected to explore attitudes and beliefs about their diabetes, role of BS and other weight loss interventions, use of the private sector, willingness to enter an RCT or preferences for particular modes.

Current research by **** involves interviews with type 2 diabetics in low IMD areas and from the South Asian community in ******, so the proposed purposive sampling strategy is felt to be feasible.

Semi-structured interviews will explore:

- experiences of managing weight whilst living with type 2 diabetes, any weight loss interventions tried
- understanding preferences and attitudes to BS and different types of BS
- how BS might affect diet, exercise and self-management of their diabetes
- the support and information they would like, in what format, when and who from, to decide whether BS was appropriate for them
- whether they would consider being randomised to different types of BS or no surgery within an RCT and what information and support would help them to make an informed choice
- interest in participating in a patient advisory group.

Interviews will be digitally recorded and transcribed as soon after the interview as possible. A reflexive log will be kept to record the researcher's perceptions of the interviews and to identify early themes to explore in later interviews.

1.3 Qualitative Interviews of Private Patients

Few patients with type 2 diabetes and BMI < 40kgm2 have undergone BS. Those that have are predominantly in the private sector. These patients will be identified from existing databases in ***** and ****. Explorative qualitative interviews will be conducted with a small group sampled at varying times post operation (n=10) to explore their decision to pay for surgery, experiences of surgery and how it has affected their lives and diabetes management.

Qualitative Analysis: the interview transcripts from patients in 1.2 and 1.3 above will be analysed using the Framework Approach.(19) This approach, through coding, charting and mapping allows the data to be explored deductively as well as inductively. In this way, findings can focus on the key questions outlined above, as well as emerging more inductively from the data.

The analysis of data will be conducted in parallel with data collection so the interview guide can be developed iteratively to explore emerging themes. The researcher will conduct the analysis. **** and other co-applicants, particularly the lay collaborator if she agrees, will code a selection of transcripts to provide inter-rater reliability.(20)

Participants will be asked if they would be interested in joining a patient advisory group to advise on:

- the development of the patient questionnaire (1.3 below)
- the content and style of information materials explaining the rationale for BS for BMI 30-40 kg/m2 and the hypothetical trial options

1.3 Questionnaire of Patient Views

Based on the findings of the qualitative phase, a questionnaire will be developed to quantify the views of patients towards the role of BS within the management of their diabetes, other weight loss strategies they have tried and their willingness to enter various designs (i.e. 2 arm, 3 arm, delayed preference) of a potential trial.

This will be mailed out to all those identified through the GPs' databases. Information materials explaining the evidence for and rationale for BS for BMI 30-40 kg/m2 and the hypothetical trial options will be included.

Sample size for Patient Questionnaire:

Estimating that an average of 20 patients will be indentified in each of the 40 practices gives a total of 800 questionnaires (formatted for electronic scanning for efficient and accurate data entry).

Estimating a conservative response rate of 50%, 400 questionnaires will be returned. Taking the primary outcome as the proportion prepared to enter a hypothetical trial and assuming it is 25%, the true proportion can be estimated to within +-5% with 95% confidence with 289 completed questionnaires . Increasing the sample to 400 will allow us to look at associations with factors such as gender and BMI (<>35).

Analysis of patient questionnaire: we will use descriptive statistics and contingency tables to explore patients' willingness to enter various designs of a hypothetical trial, their views on bariatric surgery and simple associations with ethnic, socio-demographic, age, gender and clinical factors (e.g. BMI).

Phase 2: Clinicians Views: Bariatric Surgeons, Diabetologists, GPs (Diabetic Leads) surveys 2.1)

Bariatric Surgeons: All bariatric surgeons in England will be sent the questionnaire n=100.

Consultant Diabetologists:

A random sample of 200 consultant diabetologists registered with the Association of British Clinical Diabetologists will be contacted. A previous survey had a 50% response rate. (21) With 100 responses, assuming 25% would agree to participate on a trial, the true proportion can be estimated to within +_ 8.5% with 95% confidence.

GPs Diabetic Leads: GPs from PCRNs in *** and *** n= 200

To help develop the questionnaire we will follow-up by short telephone call the lead GPs for diabetes in the 40 practices in phase 1 to elicit their views in a semi-structured interview.

The sample size has been calculated pragmatically to balance resource constraints against precision of any estimate of response rate.

Also included with the questionnaire will be:

- Information sheets presenting the evidence and uncertainties over BS in the BMI 30-40kg/m2 group with type 2 diabetes.
- Summary of findings of qualitative interviews and patient questionnaire to provide information of patients' views of BS.

Questionnaires and information sheets will be piloted with a small group of surgeons, diabetologists and diabetic lead GPs in Southampton. The questionnaire will draw on the work of Young (22) in establishing equipoise among surgeons using a postal questionnaire.

The questionnaire will ask:

- opinions on the role of BS for type 2 diabetics with BMI 30-35 kg/m2, and/or 35-40 kg/m2, all or only those with HBA1c >7.5%, or with high CVD risk on Framingham or other criteria (eg microalbuminuria)
- whether they would recommend surgery and for which types of patient
- whether they would be prepared to enter patients into a hypothetical trial
- whether they would consider even lower BMI 27.5-30kg/m2 if patient was at higher risk
- which age groups they would consider for BS
- what support would be needed pre and post operatively for these patients
- whether they would consider participating in an RCT and reasons for their decision
- preferences for the design of the trial (3 arm, 2 arm i.e band or bypass vs best medical, which type of surgery), and the reasons for their preference
- whether they favour one arm over another, and reasons for their view
- additional capacity required to provide the operations

Analysis of Questionnaires: We will use descriptive statistics and contingency tables to explore clinicians' response rates, their willingness to participate and their views on trial design. Factors of interest include volume of operations for surgeons and geographical area or IMD 2007 of practices for GPs).

Phase 3: Stakeholder Conference

A stakeholder conference will be held to present the findings and agree whether an RCT of BS in this patient group is appropriate and feasible and if so to identify the next steps required to design such a study.

Participants (approx. 30):

- Patient advisory group
- Key bariatric surgeons, diabetologists and Diabetic lead GPs
- The research team
- Selected PCT Commissioners