Research Protocol

A Feasibility Study of a Brief Intervention for Food Insecurity in Dietetic Practice

Supporting dietitians to assess for food insecurity in clinical practice

Contents

1. Background

Food insecurity is an international priority. This global issue is affecting developing and developed countries (FAO, IFAD, UNICEF, WFP and WHO 2018). 1 in 10 people within the UK are experiencing food insecurity (Taylor and Loopstra 2016). The prevalence of food insecurity is projected to increase due to continual cuts in the welfare state and introduction of universal credit. A study conducted by the United Nations looking at the food insecurity landscape in the UK identified 8.4million individuals (13%) were food insecure in 2014 (Taylor and Loopstra 2016). In comparison to other European countries the UK has the 11th highest prevalence of food insecurity (10.1%) out of 28 European countries. Put simply food insecurity is not having physical access to enough nutritious food to eat well for good health. When food becomes scarce, hygiene, safety and nutrition are often ignored as people shift to less nutritious diets and consume more 'unsafe foods' (WHO 2018). The United States Department of Agriculture (2018) use the definition of food insecurity provided by Anderson (1990) 'the limited or uncertain availability of nutritionally adequate and safe foods or limited or uncertain ability to acquire acceptable foods in socially acceptable ways'.

Food insecurity can lead to negative health and wellbeing outcomes (Gunderson and Ziliak 2015). For example, those children who are identified as food insecure are more likely to have asthma, behavioural problems and worse oral health. Mothers who are food insecure are twice as likely to report mental health problems. Diabetic adults who are food insecure are more likely to have poorer health outcomes due to the impact food insecurity can have on adherence to medical recommendations such as following a healthy diet for diabetes management (Gunderson and Ziliak 2015). New ways of tackling the increased socio-economic and health burden of food insecurity needs to be considered. Identifying and acting on food insecurity is fundamental for health professionals working in clinical practice.

Dietitians are best placed to discuss food insecurity as their consultations are focused on diet, food and nutrition, however food insecurity is not routinely discussed or screened for in UK dietetic practice. Dietetic consultations in the UK are increasingly more holistic and brief interventions to make every contact count regarding smoking cessation and physical activity are being promoted. Making every contact count refers to the opportunity every health care professional has to raise health promoting issues irrespective of the reason for the consultation (Health Education England 2018). Commonly mood, physical activity, alcohol intake and smoking status can be raised in a consultation as part of the making every contact count initiative. The evidence around brief interventions being conducted by a variety of healthcare professionals, for several health behaviours, is growing (Lewis et al. 2013). These interventions use the 3 A's approach (ask, advise and act) and should only take a moment of a consultation time.

In the US, Canada and Australia screening for food insecurity is already happening in some areas of clinical practice. The American Academy of Paediatrics released a policy statement in October 2015 that recommends all paediatricians screen all children for food insecurity. The policy statement identifies the short and long term adverse health impacts of food insecurity and recommends the referral to community resources (The American Academy of Paediatrics 2015). There is also emerging evidence in adult care that screening for food insecurity in diabetes and HIV care can have positive outcomes on treatment and now forms part of usual practice (Thomas et al. 2017 and Young et al. 2008).

However, there is little investigation of screening for food insecurity in dietitian led clinics, and no trial to test this practice has been conducted in the UK. The evidence so far suggests that this is a feasible intervention to trial. We therefore propose to test the feasibility of a brief intervention for food

insecurity in dietetic practice, by screening and referring on for food support using a food insecurity screening tool. The brief intervention will be based on the making every contact count initiative adopting an ask advise act concept. The brief intervention utilises 'social prescribing'.

2. Aims and objectives

Research aims

- To test the feasibility and acceptability of implementing a Brief Intervention for Food Insecurity in Dietetic Practice
- To explore the experience of administering a Brief Intervention for Food Insecurity from a Dietitian and Dietitian service user perspective considering opportunities and barriers.

Research objectives

- To complete a brief intervention for food insecurity in a dietitian clinic
- To complete an audio recording of some of the brief interventions to check for fidelity
- To monitor response rates for completion of the brief intervention in dietetic practice
- To complete a semi-structured interview with the dietitian service user to explore their experience (including barriers and opportunities) of the brief intervention for food insecurity via telephone
- To complete a focus group with the dietitians to explore their experience (including barriers and opportunities) of the brief intervention for food insecurity

3. Methodology

Study design

Feasibility study with mixed methods design

Intervention

The brief intervention will screen for food insecurity by a dietitian asking 2 questions to the dietitian service user. A pre-developed 2 item validated screening tool that assesses for food insecurity will be used. It uses the first two questions from the 18 item U.S. Household Food Security Survey. The two-item screen was validated by Hager et al. (2010) who reported a sensitivity of 97% and specificity 83% for identifying an affirmative response for either question. The tool has been validated in U.S as a shorter more practical tool in clinical practice. This is what The American Academy of Paediatrics (2015) endorse.

Once the dietitian has asked the two questions they will use the screening flow chart to advise why food security is important for good health and the clinical outcomes of their dietetic treatment, and then recommend what can be done to help act on food insecurity if present. To do this the dietitian will use two resources as appropriate (BDA Food Fact Sheet, Eat Well Spend Less and resource list for local food aid support). If trained, a referral voucher to a local foodbank will also be completed if appropriate. The dietitian will record the actions they take on the data collection tool.

There may be cases where a dietetic service user is recruited to participate in the study, but the dietitian does not complete the intervention (the 2 screening questions). it is important that the dietetic service user is advised how to access these food aid support resources if the intervention is not completed as their expectations may be raised that they are going to receive this information and they are not fulfilled. The dietetic service user will be advised on the participant information sheet *'Should the dietitian at your appointment not ask you the questions about food insecurity but you would like resources about this, please ask the researcher in the waiting area or contact the lead researcher (contact details on page 3) for this information'.*

STEP 1 ASK: 'I am going to read you two statements that people have made about their food situation. For each statement, please tell me whether the statement was often true, sometimes true or never true for your household in the last 12 months.

1. "We worried whether our food would run out before we got money to buy more." Was that often true, sometimes true, or never true for your household in the last 12 months?

2. "The food that we bought just did not last and we did not have money to get more." Was that often true, sometimes true, or never true for your household in the last 12 months?

A response of 'often true' or 'sometimes true' to either question is an indication of food insecurity.

A response of 'never true' to both questions is an indication that food insecurity is NOT present. Steps 2 and 3 advise and act are not required.

STEP 2 ADVISE: Once the dietitian has asked the two questions and a response of 'often true' or 'sometimes true' to either question has been provided, that is an indication of food insecurity. The dietetic service user will then be advised why addressing food insecurity is important for good health and the clinical outcomes of their dietetic treatment.

STEP 3ACT: The dietetic service user will then be recommended to access a local food support service to address their food insecure status and follow recommendations provided by the British Dietetic Associations - Eat Well Spend Less diet sheet. Literature will be provided for both aspects and will be verbally discussed. For those who cannot read they will be directed to call or access Coventry Foodbank where a volunteer will be able to discuss all the written information with them in more depth. If trained, a referral voucher to a local foodbank will also be completed if appropriate.

Training of the dietitian

The dietitian will receive specific training prior to commencing the study as per the training protocol. The principal method of delivery will be a video tutorial, designed specifically for the study, which will be available to dietitians before and during the study. The video tutorial will be a filmed consultation which will assimilate the necessary skills and confidence required of the dietitian to successfully implement the intervention. The video tutorial will address the lack of knowledge and hence confidence to intervene on food insecurity. There will also be a suggested script to follow. Also included in the training protocol is useful information about food insecurity. If there is any uncertainty about the brief intervention delivery, then the dietitian will be able to contact the lead researcher for clarification.

We need to consider the different learning styles of the dietitians. Some may learn better from reading the materials others may learn from discussing the materials with the lead researcher and others may learn better from observing the materials be delivered. Research suggests delivery of information from a blended learning approach is the best. The blended learning approach is hoped to overcome any concerns or queries the dietitian may have prior to delivering the intervention.

Fidelity checking

To examine the fidelity of the intervention, the brief intervention component of a proportion of consultations by each dietitian will be audio-recorded to ensure that the dietitian is correctly implementing the screening tool as per the training protocol (1 in 10 brief interventions will be audio recorded by each dietitian). Audio recording is less intrusive and more cost effective than

implementing video recording or observations. The aim is to produce the least invasive way of checking fidelity. We also do not want to make the participant to feel uncomfortable.

Population

Dietitian service users attending NHS dietitian led clinics in the Coventry locality.

Where possible we want to target the dietitian clinics that are ran in the most deprived areas of Coventry for example Foleshill and Hillfields. Coventry is the chosen setting for the intervention as this is where the first study for this PhD has taken place and Coventry has a good food aid support network for those in need. Coventry Foodbank is one of the largest foodbanks in England and is further developed than many UK foodbanks in relation to the additional services they provide. It has been identified as a pioneering foodbank centre that aims to educate, empower and advance the social circumstances of clients attending. This has arisen due to the high prevalence of poverty and food poverty in Coventry and the growing need for this community support service. Coventry is a marmot city.

Eligibility criteria for dietitian service user

Inclusion

- Attending dietitian clinic
- Is ≥18 years of age or their main care giver is ≥18 years of age
- Is willing and able to provide informed consent to participate and comply with the study procedures
- Is able to understand English

Exclusion

Individuals fulfilling one or more of the following criteria are not eligible to participate in the study:

- The dietitian deems it inappropriate to make an opportunistic brief intervention on food insecurity. This includes personal and medical reasons known to the dietitian or reasons related to the consultation (for example the dietitian service user has become distressed and it would seem insensitive to complete the intervention at that time).
- Is <18 years of age and their main care giver is <18 years of age
- No interpreter present, therefore the potential participant is unable to understand and speak English sufficiently to give informed consent
- Lacks capacity to give informed consent.
- Has a diagnosed severe eating disorder

Sampling strategy

Dietetic service user: purposive sampling, all dietitian service users attending dietitian clinic where the dietitian is trained to deliver the brief intervention will be invited to participate in the research

Dietitian: purposive sampling, dietitians who undertake dietitian clinics will be invited to participate in the research

Sample size

A sample size has not been predicted as it is a feasibility study. The study needs enough time to test the process and ensure that food insecure individuals are attending clinic where the research is being tested.

It is anticipated to recruit 5 dietitians and attend 10 of their clinics. Each clinic on average has 5 people in it and a 20% DNA rate. This exposes potentially 200 potential recruits to the study.

Outcome measures

1. Feasibility is to be measured by the number of dietetic service users consenting to take part, the number of completed brief interventions and the number of dietetic service users identified with food insecurity.
2. Dietetic service user's acceptability will be measured by the percentage of those identified as food insecure acting on the advice provided. This will be assessed by a telephone call from the researcher to the dietetic service user 2 weeks post intervention. The dietetic service user will also be asked about their experience of the brief intervention during this call. The telephone call will take the nature of a semi structured interview and be audio recorded. Once the telephone call is completed this will be the end of the study for the patient. 2 weeks was selected as there is no current literature to suggest a different timeframe. Self-reporting is acknowledged as a weak design however it is the most feasible and practical way of obtaining the relevant information.
3. Dietitian's acceptability of the intervention will be analysed quantitatively by the number of records of consented dietitian service users not screened. At the end of the study Dietitians will be invited to attend a focus group with other dietitians who completed the brief intervention for food insecurity to discuss the feasibility and acceptability of the brief intervention. Once the focus group has been completed this will be the end of the study for the Dietitian. A focus group is more time-efficient than completing one to one interviews and allows thoughts to be developed and shaped by peer-to-peer discussion, rather than a collection of single reflections

4. Consent and recruitment of participants

Dietitian service user

All dietitian services users attending dietitian clinics where the brief intervention is being tested will be invited to participate in the research. Recruitment of the dietitian service user will take place in the dietitian waiting area whilst they are waiting for their appointment. The potential participants will first be approached by the researcher in which a verbal explanation and a copy of the participant information sheet will be given. The dietetic service user will be provided with adequate time to consider their participation in the study. They will have time to read the participant information sheet and will have the opportunity to ask any questions they may have, in order to decide whether they wish to participate in the study or not. If the dietitian service user is willing to participate in the study, they will keep the participant information sheet and sign the consent form.

Dietitian

Recruitment of the dietitian will take place at the dietitian main department. A member of the research team will be invited to attend a department meeting to recruit. The potential participants will be introduced to the research using the participation information sheet and a verbal explanation given by the researcher. The dietitian will be provided with adequate time (with up to 24 hours) to consider their participation in the study. They will have time to read the participant information sheet and will be given an opportunity to ask any questions they may have in order to decide whether they wish to participate in the study or not. If the dietitian is willing to participate in the study, they will keep the participant information sheet and sign the consent form. They will also be provided with information on how to access the necessary training to complete the brief intervention for food insecurity.

5. Withdrawal

The participant can withdraw at any time from the study without giving a reason(s) and without their medical care or rights being affected. Data collected up to the point of withdrawal can only be used after withdrawal if the participant has consented to this.

As the dietetic service user will be asked two questions which may be considered sensitive, if the patient becomes distressed during the study they will be able to withdraw at any time, without giving a reason(s).

6. Duration

It is anticipated that the study period to gather all the necessary data will be 6 months. Study commencement July 2019. Recruitment of the dietitian to take place in July 2019. Data collection in Coventry clinics July 2019 – February 2020.

7. Analysis

Quantitative data analysis

Quantitative results will be reported using descriptive statistics, they will present the percentage of individual's eligible to take part, percentage consenting, percentage screened by the dietitian, percentage food insecure and percentage acting on advice. This data will be analysed using the statistical software package, IBM SPSS Statistics for Windows, Version 25.0 (2017).

Qualitative data analysis

A semi structured interview will be completed with the dietitian service user via telephone and a face to face focus group will be completed with the dietitians to assess the feasibility and acceptability of the implementation of the brief intervention in clinical practice, exploring the opportunities and barriers.

The semi structured interviews and focus group will be transcribed and then analysed using framework analysis. The data will be organised, analysed and coded using the qualitative software package, NVIVO 12.1 (QSR International Pty Ltd. 2018). The framework for analysis is a pre-constructed and validated coding frame called the Theoretical Domains Framework (TDF) (Atkins et al. 2017). Alongside the coding frame emergent coding will also be completed to 'mop up' any aspects of the semi-structured interviews or focus group that may not have been captured by the coding framework. A sample of the coding completed by the lead researcher will be peer reviewed by a member of the research team. Member checking will be undertaken verbally by the researcher reflecting back at the time of the focus group or semi structured interview, to check what the researcher has understood is what the participant meant.

The Theoretical Domains Framework was developed by a collaboration of behavioural scientists and implementation researchers to provide a comprehensive theory informed approach to identify determinants of behaviour. It was first developed in 2005 and then validated in 2012. It allows people to assess implementation problems and support intervention design when implementing new practices that require changes in behaviour of relevant actors. The framework provides a theoretical basis for implementation studies (Atkins et al. 2017).

Behavioural theories are relevant to investigating implementation problems and informing implementation interventions because they provide psychological processes hypothesised to regulate behaviour and behaviour change. The Theoretical Domains Framework synthesises 33 theories of behaviour and behaviour change into 14 domains (originally 12). It provides an overview of the potential influences on behaviour – cognitive, affective, social and environmental. The framework is

relevant to changing behaviours in both health professionals and patient behaviours (Atkins et al. 2017).

Reflexivity will be considered by the lead researcher writing a reflexivity chapter. The lead researcher will also keep a reflexive researcher diary throughout the process.

8. Publication and dissemination

The results of this study may be summarised in published articles, reports and presentations.

9. Funding

There is no funding for this study. The study is being completed for a PhD programme.

10. Sponsorship

Coventry University is the sponsor for the study.

11. Data protection and confidentiality

The study will comply with the current data protection regulations and regular checks and monitoring will be undertaken.

Storage of data on manual files will occur, they will be appropriately filed and stored securely. This is mainly referring to the essential documentation for the study. Confidentiality will be maintained by using a password protected university computer, anonymising all participants at the time of consent and storing manual files in a locked cupboard on an entry card protected site, to which only members of the research team will have access to. It is not anticipated that a portable laptop device will be required for this study. Contact details will be collected from the participants at the time of informed consent. The details will be anonymised and only available to the member of the research team who requires access.

Audio recording devices will be required for the study (1 in 10 brief interventions will be audio recorded for fidelity checking, dietetic service user semi structured interviews via telephone will be audio recorded and the dietitian focus group will be audio recorded). A hand-held audio recording device will be used. At the end of each day the file will be transferred to a password protected computer and the file on the audio recorder will be deleted. This data will be filed and stored securely.

Anonymity will be maintained when publishing the results. No information discussed is going to lead to individuals being identifiable. Member checking of data will be used.

12. Ethical approval and research governance

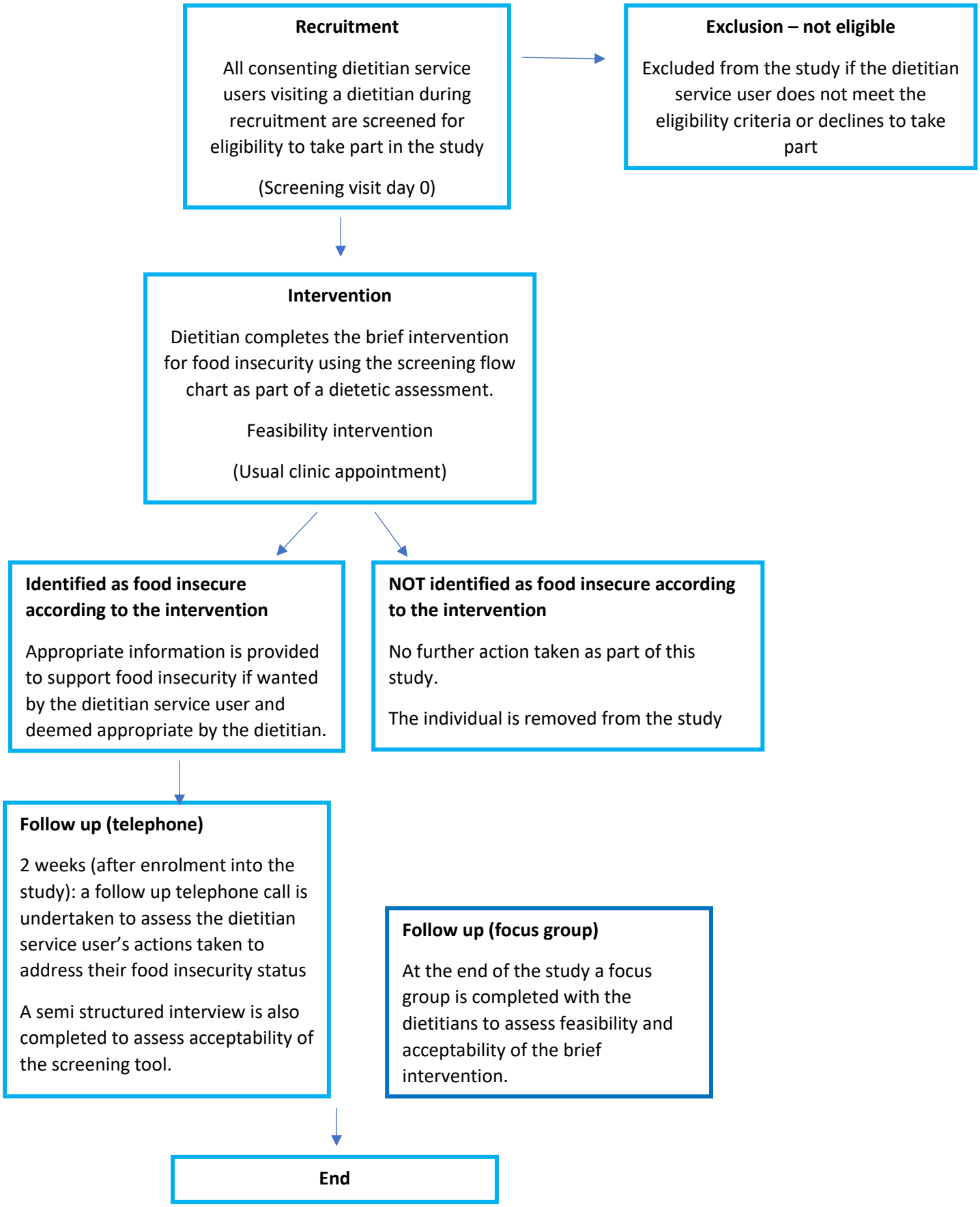
The study will be conducted in compliance with the principles of the ICH GCP (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceutical for Human Use, Good Clinical Practice) guidelines and in accordance with all applicable regulatory guidance, including, but not limited to, the UK Policy Framework for Health and Social Care Research. Ethical approval for this study will be sought from Coventry University Ethics Committee, the Research Ethics Committee (REC) combined with The Health Research Authority (HRA) approval. No study activities will commence until favourable ethical opinion and HRA approval has been obtained. Progress reports and a final report at the conclusion of the study will be submitted to the approving REC within the timelines defined by the committee.

13. Conclusion

The aim of this study is to test the feasibility of a brief opportunistic intervention for food insecurity in dietetic practice in the UK. To the research team's knowledge, no studies have investigated this feasibility.

If successful, trial results could make the case for brief interventions of food insecurity to be implemented as a simple treatment method in dietetic practice akin to the NHS stop smoking service as part of the MECC initiative.

14. Study flow chart



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