Identifying and understanding mechanisms of action in group-based health behaviour change interventions

Mechanisms of Action in Group-based Interventions (MAGI) study

Protocol Version 3

Date: 3/12/15

This protocol has regard for the HRA guidance and order of content

CONTENTS

1. FULL PROJECT TITLE

Identifying and understanding mechanisms of action in group-based health behaviour change interventions.

2. SHORT PROJECT TITLE & ACRONYM

Mechanisms of Action in Group-based Interventions (MAGI) study.

3. RESEARCH REFERENCE NUMBERS

Protocol version number and date	Version 3 2/12/15	
Funder (EME) project reference number	14/202/03	
Sponsor	University of Exeter	
Linked study acronyms and trial registry numbers	Waste the Waist: ComPoD: SkIM:	ISRCTN10707899 ISRCTN70221670 ISRCTN45134679
Linked study REC numbers	Waste the Waist: ComPoD: SkIM:	10/H0206/74 14/NW/1113 15/SW/0126
Linked study IRAS project identifiers	Waste the Waist: ComPoD: SkIM:	57779 153572 171313
Linked study NIHR portfolio/UKCRN identifiers	Waste the Waist: ComPoD: SkIM:	9846 17309 171313
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Waste the Waist: ComPoD: SkIM:	NIHR Research for Patient Benefit (RfPB) NIHR School for Public Health Research (SPHR) Public Health Practice Evaluation Scheme (PHPES) NIHR Career Development Fellowship	PBPG060919144 SPHR-EXE-PES-COM CDF-2012-05-259

4. SIGNATURES

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: ..... Date: ...../...../.....

Name (please print):.. Mrs Gail Seymour.....

Position: ... Research Ethics & Governance Manager.....

Chief Investigator:

Date: ..3../..12../..15..

Signature: ....

Name: (please print):.. Dr Jane R Smith.....

5. KEY STUDY CONTACTS

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6. STUDY OVERVIEW

Study title	Identifying and understanding mechanisms of action in group-based health behaviour change interventions.
Short title	Mechanisms of Action in Group-based Interventions (MAGI) study.
Study design	Primarily qualitative study conducted in three main stages
Study sample	Secondary data comprising recordings of group sessions from two randomised controlled trials (Waste the Waist [WtW] and Community-based Prevention of Diabetes [ComPoD]) and a feasibility study (Skills In weight loss Maintenance [SkIM]) of group-based weight loss interventions
Planned size of sample	62 recordings of group sessions
Follow up duration (if applicable)	N/A
Planned study period	January 2016 – August 2017 (20 months)
Research objectives	1. Develop a potentially generalisable framework to identify, define and categorise important group contextual factors, delivery and facilitation methods, and group-specific and group-sensitive change techniques (group processes) that may influence the effectiveness of group-based weight loss interventions, and identify any validated tools for assessing these processes (0-6 months). 2. Test and refine the framework by using it to identify, code and provide examples of instances of different group processes operating in the recordings of group sessions from three group-based weight loss interventions (6-12 months). 3. Provide explanations of why some groups may be more successful than others by mapping group contextual factors, facilitation methods and change techniques to indicators of engagement and proximal (e.g. behaviour change) and distal (e.g. weight loss) outcomes in three weight loss interventions (12 – 18 months).

7. FUNDING & SUPPORT

The study is funded via a grant for £158,360.40 from the National Institute for Health Research (NIHR) / Medical Research Council (MRC) Efficacy & Mechanisms Evaluation (EME) programme from 1st January 2016 to 31st August 2017.

Some senior staff time is supported by the NIHR Collaboration for Leadership in Applied Health Research and Care of the South West Peninsula (PenCLAHRC) and the study will also form part of the NIHR School for Public Health Research programme of work being undertaken at UEMS.

8. STUDY SPONSOR

The sponsor for the study will be the University of Exeter (contact details above)

9. ROLE OF STUDY FUNDER & SPONSOR

The sponsor (University of Exeter) and funder (NIHR/MRC EME programme) have no role in the study design, conduct, data analysis and interpretation, manuscript writing, or dissemination of results and do not control the final decision regarding any of these aspects of the study.

10. ROLES & RESPONSIBILITIES

The study researcher (Aleksandra Borek) will be supervised on a day-to-day basis by the Chief Investigator (Dr Jane Smith), who will also act as a Study Manager. Regular supervision meetings (e.g. every month to 6 weeks, depending on the stage of the research) will also be held with Prof Charles Abraham, and involve other Co-investigators on an individual basis as required at different stages of the research if particular theoretical, methodological or practical expertise or input is needed. Use will also be made of email and telephone contact, particularly with external Co-investigators, to seek on-going input or advice as needed.

The conduct and management of the study will also be overseen by:

a) A **Study Management Group** (SMG), which will comprise the Study Researcher, Chief Investigator/Study Manager, all other co-investigators and, when considered necessary or useful, one or more of the public and patient involvement (PPI) representatives, a representative of the sponsor (e.g. for consideration of Intellectual Property issues) and other advisors as necessary. The SMG will meet at the start of the study and three times thereafter i.e. approximately every 6 months. The meetings will coincide with the beginning and end of each of three 6-month stages of the research to allow findings and outputs from the completed stage to be reviewed, and allow Co-investigators and others as necessary to input to plans for the subsequent stage. The final SMG meeting will be held at the end of the third stage of the research, i.e. at 18 months into this 20-month study, to allow draft publications, other outputs and dissemination plans to be reviewed at this meeting, and finalised in the remaining 2 months.

b) A **Study Steering Committee**, which will provide independent oversight. Initially, this will comprise the existing Trial Steering Committee for the Community-based Prevention of Diabetes (ComPoD) study on which this study builds, membership of which includes:

- An independent Chair: Dr Sharon Simpson, University of Glasgow
- An independent statistician: Dr Mark Kelson, Cardiff University
- A clinician independent of the trial: Dr Phil Evans, GP at St Leonards practice, UEMS, and Primary Care Lead for the national and South West NIHR Clinical Research Network (plus availability of a further fully independent clinician for consultation on specific issues as necessary: Dr Jason Fearne-Smith, GP)
- Two Public & Patient Involvement (PPI) representatives: Mr Douglas Osborne, Mrs Sue Sedgman
- Chief Investigator for this study and the ComPoD trial: Dr Jane Smith
- Site Principal Investigators for the ComPoD trial: A/Prof Colin Greaves, Prof Janice Thompson
- Statistician for the ComPoD trial: Prof Rod Taylor
- ComPoD trial funder (SPHR) representative as necessary: Prof Charles Abraham, UEMS
- Sponsor representative as necessary: Mrs Gail Seymour, University of Exeter

With their agreement this Committee or a sub-set of its members, with additional independent expert(s) to be identified as required (e.g. a qualitative researcher), will be retained and meet beyond the end of the ComPoD study if deemed helpful to the current study.

c) **Two Advisory Groups**, comprising 1) PPI representatives (see section on PPI), and 2) facilitators involved in delivery of group-based weight loss programmes will be involved in: i) shaping the topics considered in analysis; ii) aiding in the interpretation of findings; iii) advising on presentation and reporting of results and other outputs, iv) considering implications of the findings; v) advising on, and potentially assisting with, dissemination. The Advisory Group meetings will be scheduled on three occasions to coincide with key decision points at the end of each of three stages of this study. We will also separately consult with academic experts in the field.

11. KEYWORDS

Group interventions, behaviour change, weight loss, diet, physical activity, process evaluation, qualitative research

12. LIST OF ABBREVIATIONS

BCT	Behaviour change technique
CI	Chief Investigator
ComPoD	Community-based Prevention of Diabetes trial
EME	Efficacy & Mechanisms Evaluation programme
IP	Intellectual property
LWTC	Living Well, Taking Control diabetes programme
MRC	Medical Research Council
NIHR	National Institute for Health Research
PPI	Public & Patient Involvement
SkIM	Skills In weight loss Maintenance study
SPHR	NIHR School for Public Health Research
SSC	Study Steering Committee
UEMS	University of Exeter Medical School
WtW	Waste the Waist trial

13. STUDY FLOW CHART

Jan 2016

Stage 1: Developing a framework of group processes (6 mths)

Reviews of relevant literature and other data sources:
1. Theories of group processes
2. Taxonomies of behaviour change techniques
3. Validated tools for assessment of group processes
4. Qualitative studies of participant and facilitator experiences
5. Manuals of group interventions
6. Recordings of group sessions (a diverse sample of up to 10 recordings)
7. Expert consultations (designers, facilitators and PPI reps)

Output: Draft theoretical framework of group processes and group-specific and group-sensitive change techniques

Jun 2016

Stage 2: Testing and refining the framework (6 mths)

1. Coding 28 session recordings (a sample from between and within groups)
2. Double coding and assessing reliability
3. Analysis of recordings
4. Illustrating validity by populating the framework with examples and techniques
5. Refining the framework

Output: Revised framework with illustrative examples

Dec 2016

Stage 3: Characterising more or less effective weight loss groups (6 mths)

1. Coding 24 session recordings (all sessions from 6 groups characterised by good or poor outcomes or engagement)
2. Framework analysis and construction of 'group narratives'
3. Developing explanations of associations between group processes, techniques and outcomes

Output: Explanations for mechanisms of action in group interventions

Jun 2017

Stage 4: Writing up and dissemination (2 mths)

1. Writing up study reports and publications
2. Beginning dissemination of study findings

Output: Published papers and reports

Aug 2017

14. SCIENTIFIC SUMMARY

Background: Groups are commonly used in many health behaviour change interventions. Our understanding of the mechanisms of action in these interventions is mainly based on individual-level change theories and limited meta-analyses. However, extensive research, particularly in social psychology, shows how group processes influence personal change. It is unclear, however, how these processes operate in behaviour change interventions in practice, and are influenced by group context and implementation. Therefore, a detailed analysis of what happens in group sessions is needed to enhance our understanding of change mechanisms in group-based behaviour change interventions.

Aim: Our study aims to develop a better understanding of the mechanisms of change in group-based weight loss and related behaviour change interventions. It will do this by identifying and describing group implementation processes, contextual characteristics and the operation of group-sensitive and group-specific behaviour change techniques in groups, and exploring the relationship of these with intervention outcomes.

Methods: This primarily qualitative study will proceed in three 6-month stages in line with three objectives. In Stage 1 we will develop a framework of group processes and group-sensitive and group-specific change techniques. This will be done through reviewing literature on group processes, qualitative studies, and existing tools for assessing group processes. We will pilot test and refine the framework by coding 10 transcripts of group session recordings from three group-based weight loss interventions, and will seek and incorporate feedback from experts in group interventions, and two lay advisory groups. In Stage 2 we will use the framework to code 28 transcripts of group session recordings from the same three interventions to identify examples of these processes and techniques, in order to test and refine the framework. In Stage 3 we will characterise groups in terms of group processes, characteristics, and group development, and using 24 transcripts of group sessions compare groups with better engagement and outcomes to those with worse engagement and outcomes, to identify group-specific components that might improve effectiveness of group-based weight loss interventions.

Results: The study will identify and clarify change processes and techniques operating in group settings, and provide examples of the successful initiation and use of these in three group-based weight-loss interventions. It will also provide explanations of how these techniques, processes and group characteristics may facilitate individual behaviour change and affect outcomes in these studies.

Impact & dissemination: This study will provide researchers and practitioners with a conceptual framework of how groups work in health interventions. Thus, the findings can be used to improve the design and evaluation of group-based interventions, and to train facilitators how to effectively facilitate group processes. Enhanced development and delivery of group-based interventions will benefit patients by providing better care, and the NHS by providing time- and cost-effective ways to delivering effective behaviour change interventions. Findings will be disseminated through conference presentations and publications in relevant scientific journals, and provider, practitioner and lay networks.

Timeframe: The anticipated benefits of this study are expected to occur immediately upon completion and dissemination of study findings.

15. LAY SUMMARY

Aim: Our research aims to increase understanding about how and why group programmes work to help people lose weight, and make other changes to improve their health.

Background: Many growing public health concerns such as obesity, and common health problems (e.g. diabetes), are influenced by people's lifestyles. Groups are commonly used to support people in making healthy changes to their lifestyle, including weight loss programmes. However, we know little about how or why group-based programmes work. Most of what we know comes from research and theories about individual-level change, but we know that groups can have powerful influences on individuals. Group characteristics (e.g. size, how connected people feel), how groups are led and what activities are used in groups to support people in making changes can all influence whether a group is successful or not. Based on ideas generated by participants in two previous group-based weight loss programmes, and our reviews of existing research our study aims to explore in detail what happens in group-based programmes.

Methods: We have access to over 150 recordings of group sessions from three weight loss programmes that our team were involved in evaluating. We will use qualitative research methods to examine in detail a carefully selected sample of these recordings to find out more about how groups work. We have 3 objectives and our research will proceed in three 6-month stages to address these. In Stage 1 we will develop a framework which documents and defines features of groups that may influence whether they work. This will be done by reviewing previous research and gaining feedback from experts and people previously involved in delivering and taking part in group programmes. We will try out our framework to characterise features in 10 group-based weight loss sessions and refine or add to it as necessary. In Stage 2 we will test and further develop the framework and use it to identify examples of the features we think are important in 28 recordings of group sessions. These examples might be useful in providing training on leading groups. In Stage 3 we will identify groups that have been successful in engaging people and achieving positive outcomes (e.g. weight loss) and groups that have not been so successful to try to identify features of the groups that might explain the differences. This will be done using a further sample of 24 recordings.

Results: The study will identify and clarify how group-based programmes work, particularly for weight loss. It will provide examples of the important features of groups and provide an initial explanation of how these features link to group success.

Impact & dissemination: This study will provide researchers and practitioners with a framework of how group-based weight loss programmes work. The findings could therefore be used to improve the design and evaluation of group-based programmes, and to enhance training for group leaders. Improved group-based programmes will benefit participants in them by potentially enhancing their health, and could provide the NHS and other health organisations with more time- and cost-effective ways to support people in improving their health. We will publicise our findings through conference presentations, publications in scientific journals, and via provider, practitioner and lay networks.

Timeframe: The benefits of this study could occur as soon as it is finished and the findings have been publicised.

16. BACKGROUND

Groups are used extensively to deliver health behaviour change interventions in healthcare, community, commercial, and work settings, and are often seen as the "default" mode of delivery for various health promoting programmes (1). Systematic reviews have found that group-based interventions are effective for a number of behavioural targets, such as smoking cessation (2), weight loss (3) and self-management of chronic diseases, such as diabetes (4). Particularly for weight loss, group interventions appear to be more effective than similar interventions delivered individually (5). Group-based interventions therefore provide a time- and potentially cost-effective way to address important health challenges, such as those related to growing rates of overweight and obesity. It remains unclear, however, what makes group interventions more or less effective, how short and long-term behaviour change is facilitated in groups, and what mechanisms lead to change in group interventions.

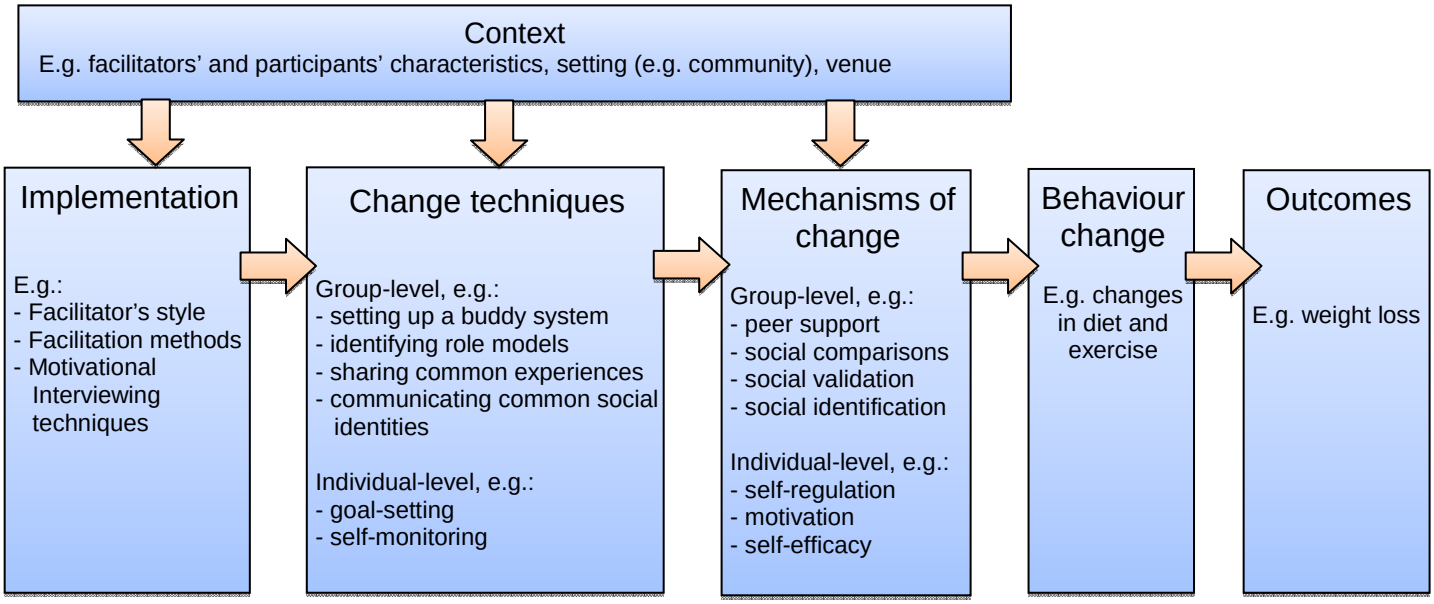
Our current understanding of change mechanisms in health interventions comes mainly from individual-level behaviour change theories and techniques (6,7). For example, self-regulatory behaviour change techniques, such as goal setting and self-monitoring, have been found to be associated with improved intervention effectiveness (1,8,9). However, groups provide opportunities to deliver change techniques that are particularly suitable for group-based delivery, such as 'providing opportunities for social comparison' or 'prompt identification as a role model' (6), and change techniques that are unique to group settings, such as 'engage group support' or 'communicate group member identities' (10). However, it is unclear how established change techniques operate in group settings and are influenced by group characteristics and processes, and what currently undefined, group-specific techniques exist. Therefore, this lack of clarity about what works, how and why is more acute in group-based rather than individual interventions.

This lack of understanding is compounded by the fact that much of the existing evidence on mechanisms of change in behaviour change interventions is based on systematic reviews and meta analyses that explore the quantitative relationships between intervention features and outcomes across previous studies (e.g. 1,8,9). Despite advantages in synthesising summary patterns of data across multiple studies, this type of research assumes that descriptions of interventions, often based on original protocols, are complete and accurate reflections of what was delivered in practice. A critical limitation of this approach, therefore, is that it cannot account for differences in fidelity or style of delivery, i.e. the extent to which the intervention was delivered in line with the protocol. Our recent review of group-based weight-loss interventions has shown that details of fidelity assessment in group session delivery, the methods used to facilitate groups, the group processes observed and the change techniques employed are rarely, or never, reported (3). Another review of group studies published in nursing journals showed that information on the conduct of groups and attempts to account for group-level effects in analyses were largely absent (11). This makes it impossible to identify the 'active ingredients' and change mechanisms in these interventions from the study reports reviewed in systematic reviews. It also makes it very difficult to accurately replicate effective group-based interventions.

Recently, MRC guidance on process evaluation (12) has highlighted that in order to understand how behaviour change and other complex interventions work, it is important to identify not only the mechanisms of action but also how intervention context and implementation interact with these to influence outcomes. These moderators of effects, however, are often omitted in studies that focus on mechanisms or mediators of effects, such as where change techniques are studied in isolation from the context and implementation. As shown in Figure 1, contextual factors, such as the group setting and characteristics of participants or facilitators, shape how interventions work by affecting their implementation, change mechanisms and outcomes. For example, the identity of a group facilitator (i.e. who the facilitator is in terms of professional or personal characteristics) may be associated with greater effectiveness for one group but less effectiveness for another, depending on the relationship between the facilitator's identity and that of the group members

(13). The characteristics of group members may also influence the effectiveness of change techniques; e.g. techniques that alter normative beliefs may be effective in promoting behavior change amongst young people but may reduce intervention effectiveness for older recipients (14). Other contextual factors that may influence how group interventions work include, for example, group climate (i.e. how positive the group atmosphere is) and group cohesion (i.e. a bond that members have with the group), which have been associated with increased attendance and self-efficacy in exercise classes (15). Similarly, factors related to the implementation of interventions, i.e. what is delivered and how, influence intervention context and mechanisms of change. For example, the use of humour in delivery of interventions has been found to be a successful facilitation technique to engage middle-aged men in a weight-loss intervention (16) but had an opposite effect among young women in a sexual health intervention (17).

Figure 1. Logic model of components influencing behaviour change and outcomes in group interventions (adapted from MRC Process evaluation guidance (12), page 10).



To guide research going forward, there is extensive literature from social psychology, education, and organisational studies on how groups work and how they influence individuals. However, to date this literature appears to have been neglected in designing and evaluating group-based health interventions (18). In particular, social psychological literature on group dynamics describes how both intra- and inter-personal processes operate in group settings (19-21). Our recent review of this literature (22) has identified a number of theories of group processes, such as social facilitation (23), social comparisons (24), social learning (25) and social identity (26) theories, that could be used to enhance our understanding of how groups influence individuals and how group context and facilitation can enhance or inhibit behaviour change in health interventions. There are similar findings from qualitative studies. For example, interviews conducted with participants in three different group-based health interventions have shown that making social comparisons, nurturing social identity, and creating a supportive and friendly group context were the key factors that facilitated participants' engagement with the interventions and lifestyle changes (27-29). However, effective facilitation of groups can be challenging, particularly for lay leaders (30), and it requires specific competencies. For example, Michie et al. (31) identified 23 facilitator competencies, such as 'encourage group discussions' or 'encourage mutual support', which are required to deliver group-based smoking cessation interventions. However, there is little evidence illuminating how such competencies are employed in practice, which might lead to inadequate training of group facilitators. There is also confusion over terminology with, for example, "encouraging social support" potentially describing a behaviour change technique, facilitation technique, facilitator's competency or another distinct group process.

An existing paper on design and delivery of group interventions in health contexts stressed the importance of employing more systematic approaches to designing and evaluating group-based health interventions (18). Although this paper provides an important first step by identifying some of the key factors in group interventions related to group leaders, participants, community and environment, it does not show how these factors are related to behaviour change techniques and mechanisms of change. To date no conceptual framework linking our understanding of group processes and personal change, on the one hand, and behaviour change techniques and change mechanisms, on the other, has been developed.

In summary, health intervention studies rarely examine how groups operate and how group processes can engender or impede personal change, and what contextual and implementation factors influence mechanisms of change and intervention outcomes. Thus the same intervention may differ in effectiveness depending on who delivers it, the characteristics of the group receiving it and on the use of different facilitation and change techniques. The most modifiable elements of group-based interventions are the change techniques that facilitators use, and their style of delivery. We do not, however, have a conceptual framework for systematically investigating what techniques are more effective in which contexts, or to understand how facilitators' styles of delivery alter the effectiveness of specific change techniques for particular audiences. This is problematic for the construction of logic models in intervention development, for the design of process evaluations, and for the training of facilitators in intervention delivery.

17. RATIONALE

As highlighted above, although group-based interventions are effective and commonly used in healthcare, their mechanisms of change, representing how or why they work, have not been systematically explored. Most current thinking about mechanisms in behaviour change interventions is driven by individual-level theories. Moreover, analyses of intervention components associated with effectiveness are mainly based on descriptions of interventions, which are often limited by a lack of comprehensive reporting and the fact they may not reflect what was actually delivered. Finally, distinctions and interactions between contextual processes, group implementation and facilitation (designed to engage participants), and change techniques, are rarely clarified and there is little evidence on how these components are manifested in practice. Only with a better understanding of the mechanisms of change in group interventions, and guidance on how important processes can be activated and facilitated, will we be able to guide development and delivery of interventions to optimise effectiveness. Starting with the MRC process evaluation guidance (12) and existing literature on group processes, this study is a first step towards addressing these gaps in the research.

We will develop a framework and methods for understanding and documenting group processes linked to outcomes, initially in the context of interventions for improving diet, physical activity and weight loss. However we anticipate that this will provide a foundation for systematically conceptualising and assessing mechanisms in group-based health interventions more generally and feed into improving the future design, evaluation and delivery of such interventions.

18. RESEARCH AIMS & OBJECTIVES

18.1 Aim and hypothesis

Our study aims to develop a better understanding of the mechanisms of change in group-based weight loss and related behaviour change interventions. It will do this by identifying and describing group implementation processes, contextual characteristics and the operation of behaviour change techniques in groups (as per key elements identified in recent MRC guidance on process evaluation), and exploring the relationship of these with intervention engagement and outcomes. Our hypothesis is that behaviour change interventions delivered in groups involve change techniques and other processes that are specific to the group setting, and which may be influenced by contextual and implementation factors. The successful initiation and facilitation of these change techniques and processes leads to increased engagement, motivation, self-efficacy, support and planning for change, and, thus, increased behaviour change (e.g. diet and physical activity) and improved intervention outcomes (e.g. weight loss).

18.2 Objectives

The objectives of this study are to:

1. Develop a potentially generalisable framework to identify, define and categorise important group contextual factors, delivery and facilitation methods, and group-specific and group-sensitive change techniques (group processes) that may influence the effectiveness of group-based weight loss interventions, and identify any validated tools for assessing these processes (Stage 1, 0-6 months).
2. Test and refine the framework by using it to identify, code and provide examples of instances of different group processes operating in the recordings of group sessions from three group-based weight loss interventions (Stage 2, 6-12 months).
3. Provide explanations of why some groups may be more successful than others by mapping group contextual factors, facilitation methods and change techniques to indicators of engagement and proximal (e.g. behaviour change) and distal (e.g. weight loss) outcomes in three weight loss interventions (Stage 3, 12 – 18 months).

18.3 Outcomes

There are no outcome measures per se in this primarily qualitative study but links between behaviour change and weight loss outcomes and group characteristics and operation will be mapped. The main outcome from this study will be an improved understanding of and method for assessing the mechanisms of change in group-based health interventions. This study will add to and build on the outputs of the original studies to provide a more comprehensive basis for researching group-based behaviour change interventions. More specific outputs will include a framework of group processes and group change techniques that can be used in designing, assessing and reporting of group interventions (Stage 1), examples of these operating in weight loss groups (Stage 2), and evidence of which group processes, change techniques and facilitation methods are characteristic of the successful weight loss groups (Stage 3). The study will feed back to the health service providers to inform future practice.

19. STUDY DESIGN

This primarily qualitative study will be conducted in three stages corresponding with the three objectives:

Stage 1. Developing a framework of group processes (0-6 months). In this stage we aim to identify and define group processes that may influence effectiveness, to integrate them into one hierarchical, conceptual framework that clarifies the differences between contextual factors, facilitation methods, and change techniques (hereafter referred to as “the framework”). We will use the ‘best fit’ approach to framework synthesis (32) and draw on a combination of literature reviews, consultation and consensus methods in developing the framework. We will update and extend our previous review of social psychological literature on group dynamics (22), review qualitative studies of participants’ and facilitators’ experiences in group programmes and identify change techniques that are particularly suitable for using in groups (group-sensitive) or that are unique to group settings (group-specific) from a sample of intervention manuals and previous taxonomies of behaviour change techniques (10,33). This will be supplemented with a review to identify any validated tools for assessing group processes or characteristics, which could be used as part of the framework.

In order to refine definitions and pilot the framework as a tool for identification and assessment of group processes, we will use it to code a “test” sample of 10 transcripts of audio recordings from sessions delivered as part of 3 studies of group-based weight loss programmes (see below), selected to ensure a diversity in the characteristics of the sessions (i.e. a range of group sizes, early-, mid- and late-stage sessions, and facilitators). If data saturation is not achieved, or if more session recordings appear beneficial for refining the framework, we will analyse transcripts of, or listen to, additional recordings. We will then identify at least 10 international experts in group-based behavioural interventions (including in fields other than weight loss) through personal and professional networks (e.g. mailing lists of the societies for behavioural medicine), and invite them to provide feedback on the framework and to identify any other important processes operating in groups. Throughout this stage we will also discuss the emerging framework with all core investigators, and two Advisory Groups comprising: (i) previous participants in one of the weight loss programmes prior to session recordings being made, who currently serve as members of a PPI group for one of the existing studies (ComPoD), and (ii) programme facilitators and related staff involved in delivery of the programmes. All feedback will be used to further refine the framework.

Stage 2. Testing the framework and providing examples of group processes in operation (6-12 months). In this stage we aim to test the usability and reliability of the framework (from Stage 1) by applying it to a larger “validation” sample of transcripts from group sessions in the three studies. This will be an iterative process in which problems of application will result in conceptual refinement and extension. Examples of each concept included in the framework will be extracted to “populate” the framework where possible, enabling us to check the reliability and validity of conceptual distinctions. We will use the framework to code (or categorise) the transcripts of recordings of around 28 group sessions (e.g. all 4 sessions for 2 groups in one study, all 6 sessions for each of 2 groups in the second study and up to 4 sessions for each of 2 groups in the third study) selected to maximise diversity in the sample in terms of facilitator, participant and group characteristics (e.g. gender mix, group size). We will also remain open to coding any other themes or instances not included previously in the framework. The coding will be firstly conducted in NVivo using a deductive content analysis approach (34) and then analysed using a framework approach (35). A sub-sample of at least 5 transcripts will be independently coded by two researchers in NVivo to assess whether the framework can be validly and reliably applied. While the proposed work is primarily qualitative and conceptual we will use quantitative methods to test the reliability of the developing framework, for example, using Cohen’s Kappa and Gwet’s AC1 measures as we have done in our previous

research (3, 22, 27). At the end of Stage 2 we will also organise a meeting with the core collaborators, and Advisory Groups (as in Stage 1) to discuss the findings, gain further feedback and undertake refinement of the framework. We will also discuss the potential for using the extracted examples of group processes in operation to develop training materials for future researchers and intervention providers.

Stage 3. Explaining why some groups are more successful than others by mapping group processes to indicators of engagement and outcomes (12-18 months). The aim of the third stage is to identify the mechanisms of impact (i.e. group contextual characteristics, facilitation and delivery methods, group change techniques) in effective as opposed to ineffective group interventions via their operation as potential predictors of intervention outcomes. A number of factors, which previously have been found to be associated with improved intervention outcomes, e.g., higher attendance (36), inclusion of specific change techniques (37,8,9), change talk (38,39), social support (40,41), and social identification (42), and other processes identified in Stages 1 and 2 will be included in these analyses. A researcher not involved in the coding and analysis will stratify and select 3 groups from the weight loss studies with high levels of engagement with the intervention (i.e. low drop-out / high attendance) and good outcomes (weight loss), and 3 groups with low levels of engagement (i.e. high drop-out / low attendance) and poor outcomes. We will analyse the transcripts of 24 group session recordings (e.g. 6 groups of 4 sessions each) by coding group processes in NVivo (using the framework developed in Stage 1 and tested and refined in Stage 2). We will also code facilitator techniques and participants' responses, for example in the form of "change talk", as outlined in analysis of motivational interviewing interventions (using the Motivational Interviewing Skill Code (MISC) (43,44). We anticipate that this will allow a sophisticated characterisation of groups within each session (e.g. in terms of facilitation methods and change techniques) and across sessions, in terms of features that only emerge when considering groups across sessions (e.g. group development features (45)). We will then compare the good and poor outcome groups in terms of within-session and across-session characterisations and examine whether differences between groups identified by our framework provide plausible explanations of good versus poor group engagement and outcomes. We do not anticipate being able to undertake a quantitative analyses of predictive elements and differences in effect sizes (though we will consider if any associations might be found using the 62+ sessions transcribed in total), but we will provide guidelines on how larger samples of group sessions could be coded and analysed to identify mechanisms and design features quantitatively associated with differences in effectiveness. Methods for this quantitative analysis could include, for example, quantifying the presence of group processes, change techniques and motivational interviewing techniques in the groups, and linking them with engagement levels and outcomes in models where other factors can be controlled for. We will also provide guidance on use of the framework in intervention design and process evaluation. Finally, we will consider to what extent the framework would require extension when applied to health behaviour change interventions that do not target weight loss (e.g., those targeting enhanced management of chronic illness). At the end of Stage 3 we will organise meetings with core collaborators and Advisory Groups again to discuss the findings. We have allowed a further two months for write up and dissemination.

20. STUDY SETTING & SAMPLE

20.1 Sources of secondary data

This study builds on two randomised controlled trials and a feasibility study of group-based weight loss interventions: the Waste the Waist (WtW), trial, Community-based Prevention of Diabetes (ComPoD) trial and Skills In weight loss Maintenance (SkIM) study. It is primarily qualitative and will use secondary data in the form of audio recordings of group sessions involving groups of 6-12 participants of mixed gender who are overweight and at high risk of cardiovascular disease and Type 2 diabetes, and in some cases their accompanying partners. These recordings were made as part of the process evaluation for the completed WtW study (n=36 sessions) and being undertaken for the ongoing ComPoD trial (predicted n=80 sessions) and SkIM study (n=88 sessions), and will be used to identify and assess mechanisms of action in these group-based interventions. A description of these studies, their participants, and the interventions evaluated is now provided.

Waste the Waist (WtW) (http://www.isrctn.com/ISRCTN10707899): The WtW study was funded by the NIHR Research for Patient Benefit programme from November 2010 to March 2013 (£239,713 awarded). Details of the study development, results and process evaluation have been published (46-48). WtW was a single site, pilot randomised controlled trial of a group based intervention designed to promote healthy eating, physical activity and weight loss for people with high cardiovascular risk in primary care.

108 adults at high risk of diabetes or heart disease were randomised to the group-based intervention plus usual care, or to usual care alone. The primary outcome was change in objective measures of weight at 12 months. Secondary outcomes included changes in diet, physical activity (assessed via accelerometers), markers of cardiovascular risk (e.g. blood pressure, blood glucose), and quality of life at 4 and 12 months.

The intervention comprised nine group sessions (four weekly 2-hour sessions in the first month, then five 1.5-hour maintenance and support sessions at increasing intervals) designed to promote motivation, social support, self-regulation and understanding of the behaviour change process. Groups of 8-12 participants, as well as partners of some participants, met in local community venues. Sessions were delivered by pairs of lifestyle coaches with varied backgrounds and experience (nutrition, physical activity, fitness/lifestyle coaching, group-based counselling) who were recruited from the local community and had been trained in delivering all intervention techniques and materials using a person-centred counselling style.

Community-based Prevention of Diabetes (ComPoD) (http://www.isrctn.com/ISRCTN70221670): The ComPoD study is ongoing, funded by the NIHR School for Public Health Research "Public Health Practice Evaluation Scheme" from July 2014 to June 2016 (£249,369 awarded, with additional contributions in cash and kind from the public health providers involved). It aims to evaluate, via a randomised, waiting list controlled trial across two sites, the clinical and cost-effectiveness of an existing, community-based diabetes prevention programme (the "Living Well, Taking Control" (LWTC) programme) being delivered by voluntary sector organisations in Devon (Westbank, westbank.org.uk) and Birmingham (Health Exchange, healthexchange.org.uk). The programme aims to increase physical activity and improve diet to promote weight loss and enhance well-being.

312 adults at high risk of developing Type 2 diabetes, were recruited via GP practices (completion of recruitment: June 2015). Following a baseline assessment, participants were randomised to either receive the LWTC programme immediately (intervention group) or after 6 months (waiting list control group). The primary outcome is change in objective measures of weight, and secondary outcomes include changes in physical activity (assessed via accelerometers), blood glucose levels (indicated by HbA1c) and self-reported diet and well-being at 6 months, with observational follow up on the intervention group at 12 months to establish whether any changes are maintained. Separately from the trial, as part of programme funding, researchers at the University of the West of England (UWE) are conducting a wider pre-post service and process evaluation of the diabetes prevention and management programmes being delivered by four voluntary sector organisations, including the two involved in the trial.

The structure, content and delivery of LWTC are compliant with all 11 NICE recommendations for diabetes prevention interventions (49) as our previous research suggests that such programmes are highly likely to be effective (37). Participants initially attend 4-6 weekly group sessions lasting up to 2 hours, which provide information on, and address common misconceptions around, 'pre-diabetes', clinical risk factors (e.g. HbA1c) and lifestyle changes to reduce risk and incorporate established behaviour change techniques (e.g. goal setting, self-monitoring). The sessions are delivered by trained facilitators with varying backgrounds (e.g. nutrition, physical activity, fitness) to groups of up to 12 participants and their partners if they choose to attend. Over the rest of the year participants receive 3 monthly then 3 quarterly individual telephone contacts, and the opportunity to access at least five hours of local community activities or services according to individual goals and needs (e.g. exercise classes, walking groups, cookery classes, smoking cessation support). The results will provide a first real-world, UK-based test of implementing NICE diabetes prevention guidance, and comprise a unique and important dataset for subsequent secondary analyses.

Skills In weight loss Maintenance (SkIM) study: SkIM is an ongoing study being undertaken in Devon during 2015-2017 as part of an NIHR Career Development Fellowship held by Prof Greaves (£744,000 awarded from April 2013 to March 2018). It is a feasibility study using an action research design and before-and-after evaluation to develop intervention materials that specifically address weight loss maintenance and integrate them into existing weight management services. The study will inform development of a future trial that will be used to evaluate the integrated intervention programme.

80 people with body mass index (BMI) >30kg/m^2 who have agreed to take part in one of two existing Tier 2 community-based weight loss programmes delivered by local participating service providers receive a group-based programme. As well as feasibility measures for a future trial including recruitment, attendance and retention rates, proposed trial outcomes being assessed include change in weight at 6, 12 and 18 months, and physical activity (assessed via accelerometers), BMI, waist circumference and self-reported health status. A process evaluation is assessing engagement, processes of change, intervention fidelity and ways in which the intervention could be improved using participant and provider interviews, questionnaires,

session recordings and observations.

The SkIM intervention augments the existing weight loss programmes, adding up to 2 additional sessions and re-scheduling the existing 90 minute sessions over 6 months instead of the current 12 weeks. This is supplemented by a self-help manual and automated telephone text reminder service. The additional contacts and materials specifically address weight loss maintenance issues based on key SkIM principles including personal assessment and management of sources of "tension" caused by making lifestyle changes and managing internal and external influences on this tension. Existing intervention providers are provided with 2 days of training and bi-monthly feedback meetings with the research team to facilitate delivery. Data gathered during a first presentation of the intervention are being used to refine the intervention, which will then be evaluated further in a second iteration.

20.2 Sample size and sampling

The total sample will be around 62 recordings of group sessions (10 in Stage 1, 28 in Stage 2, and 24 in Stage 3), including separate "test" and "validation" datasets for developing and validating the framework. The sample will include at least one session from each stage of the interventions and from each distinct set of group facilitators and groups of participants across each study. These recordings will be transcribed verbatim by an external contractor. The number of recordings is similar to sample sizes in many qualitative studies and adequate to analytic task. However, if more recordings are required to reach data saturation, additional recordings can be transcribed or listened to.

Sampling of sessions and groups will be purposive, to maximise diversity in the samples used: in Stages 1 and 2 diversity will be ensured by selecting recordings of sessions from early-, mid- and late-stages of the trials, and from groups that vary according to facilitator, participant (e.g. gender mix), and group (e.g. size) characteristics, whereas in Stage 3 the sessions will be selected to provide representation of groups with good and poor engagement (i.e. high vs. low drop out and attendance rates) and outcomes (i.e. weight loss).

21. ETHICAL AND REGULATORY CONSIDERATIONS

21.1 Risks and benefits

This study will involve secondary analysis of existing data, including audio recordings of group sessions from three existing group-based weight loss interventions (WtW, ComPoD, SkIM). The recordings have been collected as part of process evaluations for these studies, with recording of sessions expanded beyond this in the ComPoD trial to capture as many as possible for the purposes of this study. In these studies, all group participants will have given permission for sessions to be recorded and analysed, and their identities and identifiable information will be unknown to the research team. Thus, we foresee no additional risks related to the use of these recordings in this study. The work could benefit participants, intervention providers, public health policy makers and society by providing insight into how group-based health interventions work so that they can be improved and their potential to support behaviour changes and enhance health outcomes is maximised in future.

21.2 Research Ethics Committee (REC) approvals

The original NHS Research Ethics Committee approval for the Waste the Waist trial covered audio recording and analysis of recordings of intervention sessions to explore issues pertinent to the WtW process evaluation (e.g. fidelity of delivery), and separate consent from participants was sought for collection and use of these data. Since this study is essentially an extension to the process evaluation, we do not believe it raises any further ethical issues or requires additional approval. Approval for a substantial amendment to the ComPoD trial was gained in April 2015 to cover an addition to the trial protocol documenting plans to extend audio recording of intervention sessions beyond the sample previously being recorded for the UWE-led process evaluation, to capture as many groups and sessions involving trial participants as possible. Approval for the SkIM study incorporating recording of all intervention sessions was granted in July 2015. Recordings will only be made if all group participants consent. Researchers analysing the recordings will be unaware of participants' identities and will only have access to anonymous data on participant characteristics and outcomes.

21.3 Peer review

The funding application for this study and accompanying study outline (Protocol version 1) were peer-reviewed independently by five expert reviewers and one lay reviewer on behalf of the MRC/NIHR EME

programme, with funding approved on the basis of these reviews by the EME Programme Board (members are listed at: http://www.nets.nihr.ac.uk/programmes/eme/our-people). Thorough responses to all reviewer comments and questions, and subsequent Board comments and questions, were provided and minor revisions to the application and study outline were made on the basis of these. The revised version of the application and study outline (Protocol version 2) was subsequently approved by the EME Board.

22.4 Patient, public and user involvement

Previous involvement in development of research: There was no direct involvement of patient or public representatives in preparing the proposal for this study. However, Patient and Public Involvement (PPI) activities were included in the development and delivery of the WtW, ComPoD and SkIM studies on which this study builds, and the research is directly based on topics identified as important from qualitative research with participants in two related studies undertaken as part of a prior programme of PhD research which this study extends. The research questions were formulated on the basis of interviews with participants and facilitators from two group-based weight loss programmes evaluated in the WtW and Norfolk Diabetes Prevention studies. The participants believed that what happened in the groups and what the groups were like influenced their engagement with the programmes and lifestyle change. For example, participants from both studies highlighted the importance of group processes such as facilitators' style of delivery, peer support and group atmosphere and cohesion. However, there remains a gap in our understanding of how these processes are successfully instigated during intervention sessions, what makes some groups work better than others and how these processes influence individual behaviour change and related outcomes (e.g. weight loss). These were questions that the participants themselves highlighted as interesting and unanswered.

Planned involvement in study: We plan for PPI to be fully integrated into the study going forwards, and we will initially use the existing PPI Group from the on-going ComPoD trial on which this study builds to continue to develop and refine our ideas. Going forwards we plan to engage participants and facilitators from the ComPoD study in particular and will discuss and invite feedback on the findings through their participation in two Advisory Groups (one for PPI representatives, one for facilitators). The Advisory Group meetings will be scheduled on three occasions to coincide with key decision points at all three stages of this study. We will also organise separate meetings with the PPI members of the steering group in the ComPoD study to invite further feedback as necessary and one or more of the PPI representatives will also attend study management meetings if helpful. This level of involvement will ensure PPI is integral to the research and benefit the study by supplementing previous insights from individual interviews with these participants' experiences, ensuring clarity and comprehensiveness of the emerging framework of group processes and highlighting participant perspectives in analysis, interpretation and reporting. The researchers will offer support, training and links to local PPI activities (http://clahrcpeninsula.nihr.ac.uk/patient-public-involvement-in-research.php). To ensure relevance and applicability to organisations delivering group-based public health interventions we also have a public health practitioner co-investigator.

21.5 Regulatory compliance

The WtW, ComPoD and SkIM studies from which data will be used had necessary Research and Development approvals in place at all sites involved prior to recruitment of participants, delivery of the interventions and conduct of any research procedures. NHS R&D departments were informed of any substantial and non-substantial amendments as the studies progressed to ensure that necessary permissions remained in place throughout. Since we are using secondary data already collected, no further approvals are necessary.

21.6 Protocol compliance

The iterative nature of the planned research (i.e. early findings potentially influencing subsequent sampling and analyses, and later findings altering interpretations of early work) means that minor deviations from the protocol, for example in terms of the number of group sessions analysed, are to be expected. These will be documented and justified in the write up. Given the focus on conducting literature reviews, qualitative analyses of secondary, anonymised data and gathering of expert and lay input to the development of the framework for understanding group mechanisms, it is hard to envisage what might constitute a serious deviation, non-compliance or breach of the approved protocol. However, if one is suspected (e.g. breach of confidentiality) this will be reported in a timely manner to the CI and Sponsor.

21.7 Data protection and patient confidentiality

The WtW, ComPoD and SkIM studies put measures in place to ensure compliance with the requirements of the Data Protection Act 1998 with regards to the collection, storage, processing and disclosure of personal information. Any qualitative (i.e. session recordings) and quantitative data (e.g. attendance records, outcome measures) from the original studies used in this study will only be available to researchers, who were not involved in any aspects of intervention delivery, in an anonymised form with all patient identifiers removed. Participant and group identification numbers will be used to link individual and group-level data as necessary, and replace any names or other features that could make participants and groups potentially identifiable in transcript files or any write up of results. Audio files of session recordings will be stored by group identification number and session date on a secure server in a shared folder accessible only to the core study researchers, and will be retained until the write up of the study is complete.

21.8 Indemnity

Since this study is using secondary data there is no potential for harm to the research participants in the original studies, and no requirements for specialist equipment requiring insurance. The University of Exeter as the sponsor for the study will provide any other necessary professional indemnity and insurance for the duration of the research.

21.9 Amendments

Since this study did not require separate NHS REC or NHS management approval, amendments to the protocol will not require any formal notification. Any amendments will be discussed at Study Management Group meetings and subject to the approval of all co-investigators, the CI will notify the Sponsor contact and funder if deemed substantial and likely to alter the direction, importance or outputs of the research. Each new version of the protocol, key changes made to the previous version, and explanations for these will be documented in the attached Appendix 1.

21.10 Access to the final study dataset

The final dataset will be made available to all co-investigators at the end of the study and access to the dataset will be provided on an as-needed basis during the conduct of the research (e.g. for reliability checking, interpretation of findings). Requests for access to the dataset by external researchers or other organisations will be considered on a case-by-case basis by the Study Management Group and options for archiving key data in an open source (e.g. Open Research Exeter, https://ore.exeter.ac.uk/repository/) will be explored in line with funder and University of Exeter guidance.

21.11 Intellectual property

This research is built on background Intellectual Property (IP) held jointly by the University of Exeter and University of Bath for the WtW intervention, Westbank in Devon and Health Exchange in Birmingham for the LWTC programme being evaluated in the ComPoD trial and the University of Exeter for the SkIM intervention. It also builds on the IP generated by the WtW, ComPoD and SkIM studies. A joint copyright statement exists for the WtW study and an existing collaboration agreement between the University of Exeter, University of the West of England and Westbank outlines how the background IP can be used in the ComPoD trial, and specifies arrangements for ownership and exploitation of any foreground IP generated. A similar agreement will be in place for this study. All key parties have representation either directly or indirectly as a study co-investigator. For example, Mrs Jaine Keable is Head of Health and Wellbeing at Westbank, who are leading the consortium of voluntary sector organisations delivering the LWTC and in this capacity will act on behalf of Health Exchange.

In terms of IP produced or improved during this research, the study findings may lead to suggestions for refinements and additions to the LWTC programme, WtW and SKiM interventions and associated participant or facilitator training materials. These improvements will be deemed to form part of the background IP for these held by Westbank/Health Exchange, University of Exeter/University of Bath and University of Exeter respectively (i.e. we would work with the existing developers to update the interventions and the IP for the refined intervention will remain with the existing owners). It is also anticipated that the study will generate foreground IP in relation to the framework and, potentially, methods used to assess group processes and their relationship to outcomes, plus publications and possibly training materials.

A collaboration agreement signed by all parties (Universities of Exeter, Bath, and the West of England and Westbank) will be in place that recognises our collaborative working and makes explicit the arrangements

for IP ownership and exploitation, including a system for managing the emergence of IP issues not previously considered. It is anticipated that the management and exploitation of IP in relation to the interventions will be led by the existing IP owners and that the management and exploitation of IP in relation to the framework and methods used to assess group processes, and any ensuing training materials, will be led by the University of Exeter. We anticipate that any IP produced as outlined above will be of benefit to researchers, and public health/health service programme providers, policy makers and participants. Although outputs from all parties would be protected by copyright, we desire our outputs to be a) faithfully reproduced, b) disseminated without barriers and c) made available, free of charge, for use by academic researchers, the NHS, and other non-commercial public health or health service organisations, as long as we are satisfied that quality assurance procedures around their use are in place. The co-investigators therefore recognise that the production of research is not the end of the dissemination process and will drive widespread dissemination and adoption of outputs from this study with assistance from our public health partner and the ComPoD PPI group, through production of lay summaries, contacts with NHS and other public health organisations and via the NIHR School for Public Health Research and local CLAHRCs. The study Chief Investigator and researcher will be trained in IP matters if necessary and the study can also benefit, if required, from the advice of members of the University of Exeter legal team specialising in IP issues (http://www.exeter.ac.uk/campusservices/legalandinsuranceservices/legal/whoweare/). Other parties also have IP policies and legal teams to assist if necessary. The main study publications will be published in open access journals in line with NIHR policy. The outputs will be freely available once developed but we will endeavour to record user details for those downloading or requesting the detailed framework to be developed so that its impact can be tracked and data can be used for further validation. This monitoring will ensure that the benefits of the funded research and its outputs can be captured. We also highly prize impact in terms of participants' experiences and outcomes and will request feedback from individuals or organisations using the framework, to record any changes in practice, service delivery, cost savings or participant feedback.

Having consulted with the University of Exeter's Research and Knowledge Transfer department we believe that any foreground IP generated is unlikely to be patentable and any materials and methods will be subject to copyright protection. IP will vest in the University of Exeter and the other parties will be granted a non-exclusive, royalty free licence to use the foreground IP in perpetuity for non-commercial research, clinical, training and teaching purposes. In the event that any party wishes to commercialise the foreground IP the parties will seek to put in place a revenue sharing agreement subject to written consent of the Department of Health.

22. DISSEMINATION

22.1 Dissemination plans

Key beneficiaries of this research include other researchers, NHS and other providers of group-based weight loss and related public health programmes, public health policy makers at regional and national level who might use study outputs to inform future training of providers and delivery of activities, and ultimately participants in group programmes. Findings will be disseminated using multiple channels to ensure these groups are reached:

a) **Academic publications:** We plan to publish at least 3 papers presenting the framework and methods developed, and findings from each stage of the research in high impact behavioural medicine/public health journals (e.g. Annals of Behavioral Medicine, Preventive Medicine, Social Science & Medicine, BMC Public Health). The budget includes fees to ensure at least some are available via open access.

b) **Presentations:** Findings will be presented at international (e.g. International Society of Behavioral Medicine), national (e.g. UK Society for Social Medicine, UK Society for Behavioural Medicine, UKSBM) and regional (e.g. South West Public Health) conferences, internal seminars and relevant events organised by local public health organisations. Funding to attend one key international and national conference is requested. Attendance at others may be supported via concurrent presentation of findings from the linked studies (e.g. the ComPoD trial).

c) **Websites, mailing lists, social media:** We will add updates and links to reports, presentations and publications to our own personal and departmental websites, and publicise and gain feedback on these via our own universities' media channels and links with organisations such as the UKSBM, PenCLAHRC, CLAHRC West, NIHR School for Public Health Research, National Obesity Forum, National Obesity

Observatory and other relevant Public Health England agencies and networks, and the CHAIN network for staff working in health and social care (http://chain.ulcc.ac.uk/).

d) Press, public health provider and PPI networks: With the support of University press offices, our PPI representatives and public health provider partner we will produce lay summaries of plans, progress and findings and related press releases for use in local media and dissemination via their relevant networks, including those involving voluntary sector organisations, patient support groups etc. Advice on dissemination to lay and non-specialist audiences will also be sought from the PenCLAHRC PPI Group (PenPIG).

22.2 Anticipated outputs

There will be at least three specific outputs from this study related to the three objectives and three study stages:

a) A conceptual framework of group processes which can be used by other researchers studying behaviour change interventions, by those designing group-based behaviour change interventions, and by intervention providers.

b) Examples of group techniques, facilitation methods and contextual operating in group-based weight loss interventions. These findings can be used in developing training materials for group facilitators to ensure good quality of session delivery.

c) Explanation of how and which group processes, change techniques, facilitation methods, and group characteristics seem associated with more or less effective groups (in terms of engagement and outcomes). These findings can be used as a first step to systematically link group processes and techniques with intervention outcomes.

Moreover, the study will have impacts via dissemination of results to academic, health provider and practitioner audiences:

d) Conference presentations (at least one national and one international conference for behaviour change researchers and practitioners).

e) Journal articles (at least 3 articles in peer-reviewed journals, and reports disseminated to lay and practitioner audiences).

The outputs of this study will provide a conceptual framework and recommendations for design of group-based behaviour change interventions, new methods for process evaluations of group interventions, and materials for training of intervention facilitators. Thus, it will contribute to the development of more effective interventions and evaluation of current interventions delivered in group settings. This, in turn, will benefit the patients by helping them improve their health and well-being.

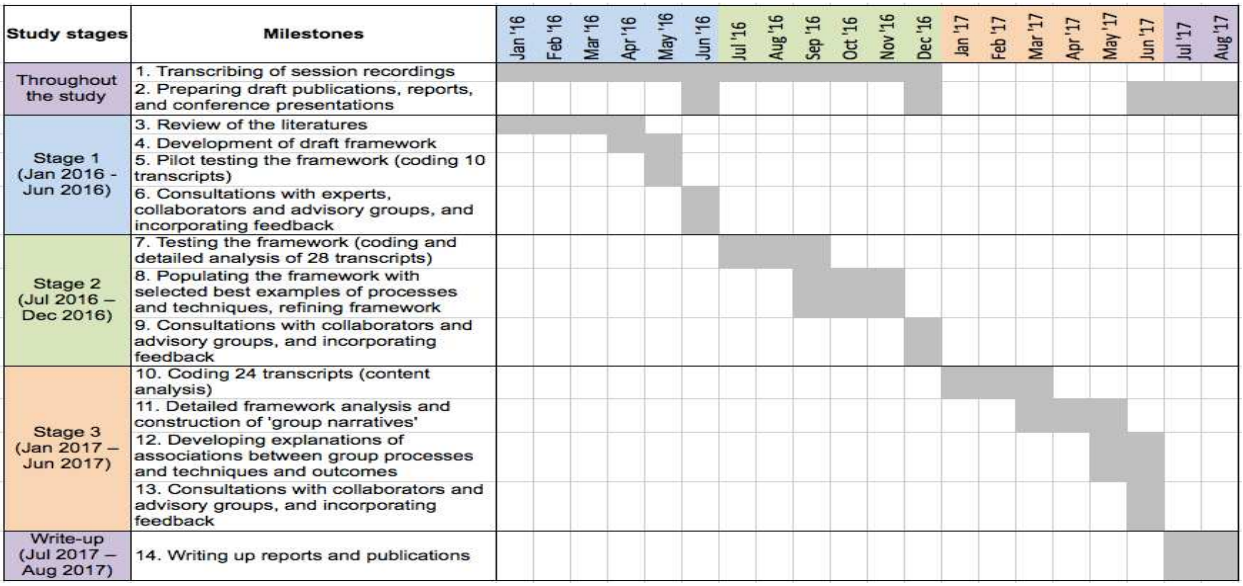
22.3 Authorship eligibility guidelines

The write up will be undertaken by the study team. Authorship eligibility will be based in the International Committee of Medical Journal Editors criteria for manuscripts submitted for publication and discussed and agreed at Study Management Group meetings in relation to each output.

23. PROJECT TIMETABLE, MILESTONES AND GANTT CHART

The study will commence in January 2015 and last 20 months (until the end of August 2017). It will be divided into 3 stages corresponding with the 3 objectives, each of them lasting 6 months and allowing 2 months at the end of the study to write up research findings and reports. The tasks to be conducted in each stage and key milestones are show in Figure 2 below.

Figure 2. Gannt chart showing project timetable, and key tasks and milestones



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APPENDIX 1: PROTOCOL AMENDMENT HISTORY

Protocol version no.	Details	Date issued	Author(s) of changes	Details of changes made
Version 1	This was the project outline submitted with the original funding application.	10/2/15	N/A	N/A
Version 2	This was the project outline submitted with the revised funding application.	18/9/15	JS, AB, CG	The main changes reflect the proposed use of an additional dataset of recordings now available from the SkIM study, which will enhance the richness of the data and generalizability of the research. Details of this study were added in relevant sections, references to the study were incorporated where data sources and analyses are described, and the number of recordings to be analysed in one stage of the research was slightly adjusted (from 24 to 28 in this stage and 58 to 62 overall) to accommodate use of the SkIM recordings. Details of timelines provided in the text and protocol have also been adjusted to reflect a 1st Jan 2016 start date.
Version 3	This is the version submitted to the funder prior to the project start date.	3/12/15	JS	The previous version was revised and expanded in line with Health Research Authority guidance and template for protocols of qualitative studies (http://www.hra.nhs.uk/about-the-hra/consultations-calls/closed-consultations/qualitative-protocol-guidance-and-template/). Additions mainly reflect inclusion of text from the original funding application form

				which could not be included in the previous 10-page project outline (e.g. dissemination plans), and re-structuring in line with recommended headings.