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Title: Making a Move in Exercise Referral: Co-Development of a *Physical Activity* Referral Scheme

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Adherence to ethical principles: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee. Informed consent was obtained from all individual participants included in the study. NHS Research Ethics Committee approval was received for this study on 06 April 2016 (REC reference: 16/EM/0157 - Project number: 204481).

The findings/data reported in this study have not been previously published and the manuscript is not being simultaneously submitted elsewhere. The authors have full control of all primary data and they agree to allow the journal to review their data if requested.

ABSTRACT

Background.

Translational research is required to ensure Exercise Referral Schemes (ERSs) are evidence-based and reflect local needs. This paper reports process data from the co-development phase of an ERS, providing an insight into a) factors that must be considered when translating evidence to practice in an ERS setting, and b) challenges and facilitators of conducting participatory research involving multiple stakeholders.

Methods.

An ERS was iteratively co-developed by a multidisciplinary stakeholder group (commissioners, managers, practitioners, patients, and academics) via five participatory meetings and an online survey. Audio data (e.g. group discussions) and visual data (e.g. whiteboard notes) were recorded and analysed using NVivo-10 electronic software.

Results.

Factors to consider when translating evidence to practice in an ERS setting included 1. Current ERS culture; 2. Skills, safety and accountability; and 3. Resources and capacity. The co-development process was facilitated by needs-analysis, open questions, multidisciplinary debate, and reflective practice. Challenges included contrasting views, irregular attendance, and (mis)perceptions of evaluation.

Conclusion.

The multidisciplinary co-development process highlighted cultural and pragmatic issues related to exercise referral provision, resulting in an evidence-based intervention framework designed to be implemented within existing infrastructures. Further work is required to establish the feasibility and effectiveness of the co-developed intervention in practice.

INTRODUCTION

Physical activity (PA) as medicine is well-established[1,2] yet attempts to translate this evidence to practice have seen limited success.[3] This may, in part, represent a lack of practitioner and patient involvement in intervention development and implementation.[4] Whilst highly-controlled efficacy trials represent the gold standard in academic research, they provide limited information for policy-makers and practitioners when implementing interventions in the "real-world".[5] If sport and exercise medicine is to inform the development of ecologically valid PA interventions, alternative research methodologies are urgently needed.[6]

This study forms the initial phase of a project aimed at co-developing and evaluating a novel, evidence-based exercise referral scheme (ERS). ERSs provide a promising framework to support PA behaviour change in inactive individuals with health conditions.[7,8] In 2011, there were estimated to be over 600 ERSs in operation across the UK, which typically involve a health professional referral to a 12-week exercise programme.[3] In the current study location, an existing ERS (run by the local authority) followed a model of 12 weeks of subsidised exercise at a local fitness centre. An evaluation of the ERS revealed that, despite some patients reporting health benefits, there was limited contact from instructors (58% patients met their instructor once only) and few attempts to promote long-term PA behaviour change.[9] These findings echo systematic review data, which demonstrates many ERSs lack behaviour change components, fail to collect long-term outcome data,[3] and report wide-ranging uptake and adherence rates (28-100% and 12-93%, respectively).[10] Consequently, evidence of effectiveness is scarce and systematic reviews have been deemed an unfair assessment of the *potential* of ERSs to impact public health.[11] To improve implementation and effectiveness of interventions to support long-term PA behaviour change, there is a need for ecologically valid, multi-stakeholder developed interventions[12,13] that reflect the pragmatic needs of end-users.[14]

The Medical Research Council recommends a phased approach to the development of complex interventions,[15] starting with a development phase, followed by piloting to ensure the intervention is

refined sufficiently, before undergoing an effectiveness trial. Participatory research has been described as moving away from a 'them and us' mentality and involves actively engaging stakeholders from all levels (patients, practitioners, and policy-makers) alongside academics in the co-development of interventions.[16–17] Multi-stakeholder involvement provides important insights into the feasible implementation of interventions in the "real-world", in turn leading to interventions that are context-sensitive, effective and sustainable within local infrastructures.[12,18] The purpose of this paper is to report process data from the participatory co-development phase of an ERS in a large city in the North-West of England, providing an insight into a) factors that must be considered when translating evidence to practice in an ERS setting, and b) challenges and facilitators of conducting participatory research involving multiple stakeholders.

METHODS

Participants

A purposive sampling approach was used to identify multi-level stakeholders who were involved with the current ERS in operation in the city. A development group was consequently formed consisting of public health commissioners (*n*=4), a fitness centre area manager (*n*=1), general practitioner (GP; *n*=1), exercise referral practitioners (ERPs, *n*=2), health trainer (*n*=1), health trainer coordinator (*n*=1), patients (*n*=5), plus academic experts in exercise referral (*n*=1), exercise psychology (*n*=1,) and exercise physiology (*n*=1). The role of academic group members was to provide theoretical knowledge and scientific evidence, whilst local stakeholders contributed vital local knowledge and experiences to inform the pragmatic feasibility of the intervention.[19]

Participatory Research Process

The described methodology draws on a conceptual model of healthcare service co-production.[20] Further, the pragmatic methods draw on previous experiences of complex intervention development,[21,22] focus group facilitation[23,24] and autonomy-supportive workshop provision.[25]

Participatory meetings. Five development group meetings (2-3 hours) were organised between April and August 2016 to facilitate the iterative development of the intervention (Table 1). Objectives were pre-determined for each meeting, although content and timescales evolved based on discussions in preceding meetings. Each meeting was facilitated by a member of the research team [LG], whose specialist area was not in exercise referral. Within each meeting, small-group activities (4-5 participants per subgroup) were used to facilitate collaboration and ensure all stakeholders were given a voice. Each subgroup was presented with open questions to discuss and asked to record their views on a flip chart. Following subgroup activities, a whole group discussion collated the issues raised in relation to each meeting's objectives. Efforts were made to facilitate co-development throughout by providing a clear rationale for decisions and tasks, and structuring activities to allow the development group to come up with their own solutions.

In addition to the core development meetings, e-mail correspondence facilitated preparations and planning for the development meetings, allowed the research team to clarify specific discussion points following the meetings, and provided evidence of commitment/agreement from specific individuals in writing. Once the intervention framework was agreed, continued liaison with group members (via e-mails, one-to-one and small group meetings) allowed the more detailed components of the scheme to materialise.

Online survey. To ensure stakeholder views had been accurately interpreted, participants were given the opportunity to complete an online survey to confirm their individual agreement of intervention components (e.g. aim, eligibility, exclusion criteria, outcome measures, behaviour change support).[20] Participants were also asked about their experiences of the process and to what extent they felt their views were valued and acted upon.

Table 1.

Table 1. Summary of development meeting content collected between April and August 2016 in Liverpool, UK.

Development Meeting	Objectives	Tasks / Key Questions
1. Needs analysis (April 2016)	• To gather stakeholder views on strengths and areas for improvement of the current ERS in operation in the city (Exercise for Health (EFH)). • To discuss potential aims and objectives for the new ERS.	• "What should be the aim of a scheme?" • "What positive factors of EFH would you like to keep?" • "What issues with EFH would you like to change/develop?" • "What changes could be made to address these issues?" • "What needs to happen to enable these changes to take place? (E.g. training, resources, communication)".
2. Eligibility and referral (April 2016)	• To attain preliminary thoughts from the stakeholders regarding eligibility for the scheme. • To gain perceptions of what the referral pathway should look like (i.e. the professionals a patient will need to meet before they can uptake the scheme).	• "Who is the scheme for?", • "Who can refer?" • "What will the referral pathway look like?" • A summary of eligibility guidelines from NICE [34] was presented to the group to support discussion.

3. Intervention framework (stage 1) (May 2016)	• To address the structural components of the referral scheme e.g. how much contact participants will have, how participants will be supported during the referral scheme, and who will deliver the behavioural change aspects of the programme.	• Prior to the meeting, the research team created a preliminary intervention framework based on discussions during meetings 1 and 2. • The framework was then shared with the group to discuss issues of delivery and feasibility, and to inform further refinements to the proposed model.
4. Intervention framework (stage 2) and evaluation (May 2016)	• To refine the intervention framework based on meeting 3 discussions. • To determine how the intervention would be evaluated.	• A refined intervention framework was developed by the research team based on meeting 3 discussions and presented to the group. • To gain further feedback for the refined ERS framework from the development group. • Discussions explored how the ERS would be evaluated and what outcome measures would be embedded into scheme delivery.
5. '*Follow-Up'* development Meeting (August 2016)	• Primary objective: to summarise the outcome of the process thus far, check for consensus, and gather further comments prior to piloting the scheme.	• Discuss and check for consensus on data that had been analysed from the development meetings, online survey responses, and supplementary meetings.

• Secondary objective: to maintain contact and engagement with key stakeholders.	• Make any necessary changes before piloting the intervention.

Data Collection and Analysis

Multiple qualitative methods were used to document the intervention development process and capture audio and visual data relevant to the research objectives. The first author [BB] attended each meeting to collect data via audio recordings, observation, reflective notes, and photographs of white board and flip chart content.[26] Reflective practice was used throughout the development process by the research team.[27] Since the iterative methods did not lend themselves to a traditional qualitative analysis, the analysis aimed to capture the processes the stakeholder group went through and the challenges that arose when translating evidence to practice in an ERS setting. Data from audio-recordings (verbatim transcriptions), visual records (e.g. white board notes) and researcher reflections were organised using NVivo-10 electronic software (QSR International 2002), then meaningful excerpts extrapolated relevant to the research questions.[28] When analysing participant interaction, key principles of focus group analysis were followed to ensure interaction between group members was captured.[23,24] Primary analysis was conducted by the first author [BB], with frequent debriefing sessions[29] with research team members [LG and PW] to discuss and debate emerging data, and inform the development of subsequent participatory meetings. As details of intervention components emerged, they were iteratively mapped to the Template for Intervention Development and Replication (TIDieR) checklist.[30] This was a systematic process to ensure the co-developed framework was evidence-based and mapped to local priorities.

RESULTS

What factors must be considered when translating evidence to practice in an exercise referral setting?

Throughout the development meetings, debate among stakeholders raised three key issues that required consideration when translating evidence to practice in an ERS setting: 1. Current exercise referral culture; 2. Skills, safety and accountability; 3. Resources and capacity.

Current exercise referral culture

There was consensus among policy-makers, practitioners and patients that the ERS should have a *'person-centred'* approach, with a focus on improving *'whole person wellbeing'* through *'sustainable'* increases to PA. Yet, this emphasis on lifestyle PA behaviour change was not reflected in the current ERS culture, built around fitness centres and fixed-term exercise prescriptions (usually 12-16 weeks). Thus, it was deemed a cultural shift was required from the typical UK 'exercise referral' scheme to a more holistic 'PA referral' approach.

Skills, safety and accountability

Having established the importance of a PA behaviour change focus, consideration needed to be given to *how* such support could be embedded into a new ERS within existing resources. Initially, stakeholders agreed that a Health Trainer service [UK initiative that employs lay health workers to provide individualised behaviour change support for a broad spectrum of health issues] could act as the primary referral route and provide behaviour change support to patients. "*They* [Health Trainers] *are very skilled, they're very good at working with people and supporting them, so that makes a big difference, having the right type of people…*" (ERP). Whilst Health Trainers have the requisite skills to provide such support, they are not qualified exercise professionals. This created a tension within the multi-stakeholder group to determine who could "sign patients off" to do lifestyle-related PA. Whilst the fitness centre manager reported a *"higher duty of care"* and emphasised a legal requirement for

anyone prescribing PA to have an exercise referral qualification, others in the group took a "common sense" viewpoint:

> "*We don't need to get risk-averse here… we've got to give responsibility to the patient… otherwise it would become unworkable, and at what point is that realistic? Are you going to say to someone, 'you can't run for the bus once you leave here', clearly they can, it's up to them"* – GP and Public Health Commissioner.

Due to a lack of clear guidance on this issue, the stakeholder group concluded that it was necessary for qualified ERPs to assess all patients and provide appropriate PA advice. Consequently, ownership of the new ERS would remain with fitness centres.

Resources and capacity

Figure 1 demonstrates the preliminary ERS framework that was presented to the development group in meeting 3, drawing on previous discussions about PA behaviour change and accountability. The framework involved baseline and post-ERS assessments with an ERP, followed by bi-weekly behaviour change support from a Health Trainer.

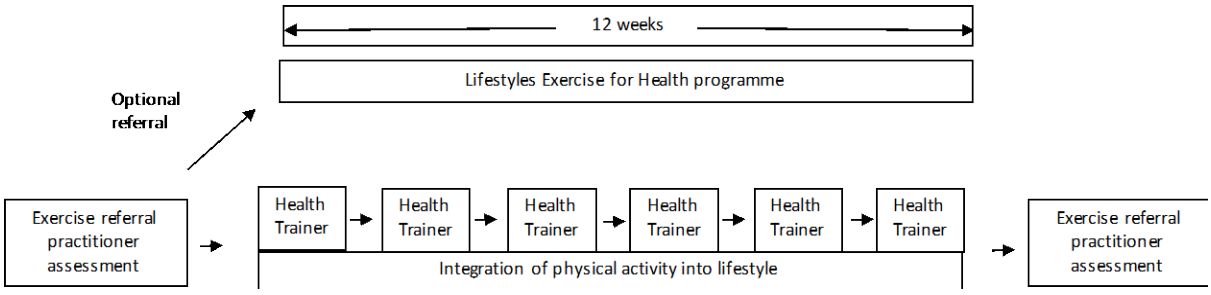

Figure 1. Flow diagram of a preliminary intervention framework for a PA referral scheme, co-developed from participatory meetings 1 and 2 (April 2016, Liverpool, UK). The framework was underpinned by the identified importance of focussing on PA and incorporating behaviour change support, the involvement of a Health Trainer service, and solving accountability concerns (i.e. ERP assessments pre- and post-intervention).

Figure 1.

Whilst the preliminary ERS framework was positively received by some stakeholders ("*It is easy to understand why this level of support would be beneficial for patients*"- Public Health Commissioner), patients felt the proposed level of bi-weekly support *"may not always be necessary and* [may be] *potentially intrusive"*. Furthermore, there were fears that the level of support proposed was time and resource intensive. It became apparent that the Health Trainer service would not have capacity to adopt the proposed role. Whilst the preliminary framework was evidence-based and co-developed by local stakeholders, subsequent discussions highlighted a lack of congruence between the perceived "ideal" (i.e. what would be delivered to produce optimal results) and the "real" (i.e. what could feasibly be delivered within current resources).

Stakeholder responses to the preliminary framework informed an adapted intervention model (Figure 2). It was acknowledged (by both ERPs and a fitness centre manager) that, with the appropriate training and support, ERPs *"could do more"* within their roles to support patient PA behaviour change. It was agreed that this approach (Figure 2) was the most viable model for translating evidence to practice within local resources. The final ERS framework is described in detail in supplementary resource 1 (TIDieR checklist) and supplementary resource 2 (theoretical underpinning of behavioural change components).

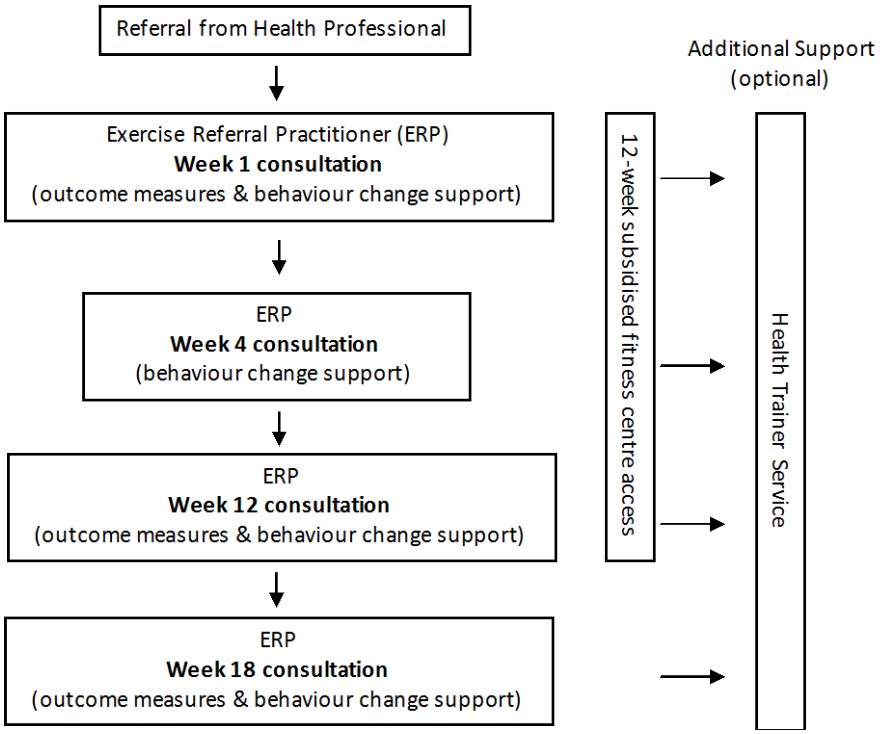

Figure 2. Overview of the PA referral scheme framework co-developed between April and August 2016 in Liverpool, UK. Fundamental adaptations from the existing scheme in operation were: a unified focus on lifestyle PA and not 'just structured exercise' per se; additional consultations at week 4 and week 18; structured behaviour change support delivered by ERPs; optional supplementary support from a Health Trainer service for additional health behaviours (e.g. nutrition, smoking, alcohol etc.); and collection of patient-determined evaluation data (e.g. PA, psychological wellbeing, body mass). The target population will be inactive individuals with health-related risk factors or conditions aligned with NICE recommendations [34]. Behaviour change consultations will be underpinned by Self-Determination Theory [30] and will include a range of behaviour change techniques.

Figure 2.

What are the facilitators and challenges of conducting participatory research involving multiple stakeholders?

Table 2 provides a summary of the perceived facilitators and challenges that arose during the co-development process of an ERS.

Table 2.

Table 2. Summary of pragmatic facilitators and challenges of a participatory research process (April-August 2016, Liverpool, UK)

Facilitators	Challenges
• Using the first meeting as a 'needs analysis' allowed the stakeholders to share their perceptions of the existing scheme and expectations of the process. • Open questions and use of sub-groups facilitated input and discussion from stakeholders ensuring that their knowledge and experience informed the intervention. • Multidisciplinary debate and problem solving allowed for various areas of expertise and experience to inform the intervention. • Reflective practice contributed to the iterative intervention development and facilitated knowledge translation.	• Multidisciplinary group discussion meant that occasionally, different stakeholders had contrasting views on a topic that were not always resolved. • Irregular stakeholder attendance meant content had to be repeated for participants who missed previous meetings. • (Mis)perceptions of the evaluation process: Stakeholders may have initially seen evaluation as solely an academic agenda rather than an attempt to align the intervention to NICE exercise referral scheme guidance.[31]

Commencing the development phase with a needs analysis allowed the stakeholders to share their perceptions of the existing scheme, ideas for change, and in turn, ensure the intervention development was stakeholder-driven. This sense of co-ownership was verified via online survey responses (n=11), whereby 100% respondents felt they had been given the opportunity to share their views and 89% respondents felt their views had been acted upon "very much" (the other 11% answering "somewhat"). Although, working with such a diverse group exposed contrasting views, which required skilled facilitation (e.g. open questions, subgroup discussions) and additional consultation procedures (e.g. email correspondence and one-to-one meetings) before a consensus could be reached. Stakeholder debate allowed an essential problem-solving process to occur, preventing unrealistic demands and enhancing potential for future implementation success.

During the participatory process, some stakeholders appeared to view evaluation as solely an academic agenda. When discussing how evaluation measures might be embedded within the intervention, a commissioner indicated that the primary purpose of collecting data was to meet academic requirements *("I think the point of the study is, you've* [research team] *got to get the data"*). In response, researchers highlighted the National Institute of Health and Care Excellence guidance[31] that stated ERSs should collect evaluation data beyond the research period.

DISCUSSION

MAIN FINDINGS

The aim of this paper was to report process data from the participatory co-development phase of an ERS in a large city in the North-West of England. Translation of evidence to practice in an ERS setting raised several issues, including the current ERS culture, skills, safety and accountability and resources and capacity. A secondary aim was to explore challenges and facilitators of conducting participatory research involving multiple stakeholders. Facilitators included needs analysis, open questions, use of

sub-groups, multidisciplinary debate, and reflective practice. Challenges included contrasting views, irregular stakeholder availability, and (mis)perceptions of the evaluation process.

WHAT IS ALREADY KNOWN

According to systematic review findings, the effectiveness of ERSs is unclear.[3] Yet, these conclusions have been drawn from evaluations of interventions that are rarely evidence-based, are not underpinned by behaviour change theory, and have not been developed to an extent where they are likely to elicit meaningful public health impact.[15] Further, the appropriateness of randomised-controlled trials to evaluate complex public health interventions has been questioned.[32] There is an urgent need for translational research methods that enable the development of evidence-based, yet ecologically valid ERS approaches. Co-production methods have been advocated as a means of maximising the likely impact and sustainability of complex public health interventions.[20]

WHAT THIS STUDY ADDS

This is the first known study to apply co-production methods within an ERS setting. The study provides new insights into a) factors that must be considered when translating evidence to practice in an ERS, and b) facilitators and challenges of participatory research when co-developing a complex public health intervention with a multidisciplinary stakeholder group. Findings highlighted a need for a cultural shift to update ERS provision to a PA behaviour change approach, with stakeholder discussions identifying a number of issues that must be considered to enable this to happen.

It was noted that the aim of the intervention should be on changing individual *PA behaviour*. Whilst this aim was in line with the World Health Organization guidance (e.g. 150 minutes of moderate intensity PA per week),[1] it meant a shift from "exercise prescription" to a focus on "PA behaviour change support". Despite the National Quality Assurance Framework (NQAF)[33] advocating that ERSs should go beyond "*advice giving, recommending exercise, or offering patients vouchers to attend exercise facilities"* (p. vii), the majority of UK ERSs continue to offer 12-16 week exercise prescriptions and few exercise referral practitioners are trained to provide behaviour change support.

Consequently, exercise referral requires a cultural shift to align PA provision with World Health Organization guidance[1] and consideration needs to be given to behaviour change training and education for ERS providers.

Given the lack of behaviour change expertise and limited staff capacity within local fitness centres, stakeholders within our co-development group proposed involvement from the Health Trainer service, who were deemed well placed to provide behaviour change support. This, however, raised the issue of whether Health Trainers [who have no professional exercise qualification] could or should hold responsibility for providing PA advice to patients with health conditions. The NQAF stated that when an individual with health-related risk factors is specifically referred for an exercise intervention, *"responsibility for safe and effective design and delivery of the exercise programme passes to the exercise and leisure professionals"* (p.13).[33] These exercise professionals should be registered with a national body (e.g. level 3 Register of Exercise Professionals qualification) and have indemnity in respect of their work. Conversely, NQAF also noted that *"recommendations to be habitually more active"* (p.11)[33] may be provided by non-exercise professionals, a consensus supported in a recent Canadian position statement.[2] Where patients have conditions classified as high-risk, however, both the NQAF[33] and Canadian position statement[2] advocate referral to a qualified professional. This distinction creates a grey area for ERSs that are centred towards habitual PA recommendations, yet target at-risk populations. The greatest public health gains may arise through small increases to daily PA.[34] Yet, it is unviable and arguably unethical for professionals to control patients' habitual PA. Indeed, extensive evidence suggests that if patients feel autonomous in their PA, they are likely to have improved long-term adherence.[25] Consequently, clearer guidance is needed to determine who holds responsibility for patient safety within ERSs that focus on PA behaviour change.

Co-production is a promising tool for public health services, however, associated challenges need to be considered. The inclusion of multiple levels of engagement is fundamental for a participatory development process.[16] In practice, this requires leadership, a tolerance of messiness, and careful negotiation of group politics (particularly when the group involves natural power imbalances e.g.

commissioners and service providers) to be able to have productive discussions that result in meaningful actions.[35] We found that commencing the co-production process with a 'needs analysis' was an important step to facilitate a consensus for an appropriate agenda and well aligned outcome objectives.[36] Multidisciplinary debate allowed diverse areas of expertise to inform the intervention, whilst reflective practice enabled researchers to make sense of debate and inform the iterative development of the intervention.[26,28] Finally, there may be times when a conceptual gap emerges between stakeholder and researcher desired outcomes. In the instance of disagreement, discussion of differences between stakeholders should be encouraged, and the involvement of the wider community should be viewed as a resource, not a threat.[34]

LIMITATIONS

Detailed reporting on intervention development is vital for the advancement of effective behaviour change interventions.[37] The purpose of this study was to report process information of a co-development approach that may lead to improved chances of implementation success. Therefore, conclusions cannot be drawn regarding the effectiveness of this approach, on the future intervention outcomes or its sustainability. Inconsistent stakeholder attendance meant that not all stakeholders provided input to all meetings. Therefore, where individuals missed meetings, subsequent attempts were made to gather their views through informal conversations and an online questionnaire.

CONCLUSION

Systematic reviews have demonstrated that ERSs typically lack behaviour change components, fail to collect long-term outcome data,[3] and report wide-ranging uptake and adherence rates.[10] Yet, such conclusions have stemmed from interventions that have not been developed with local stakeholders to a point where they can be expected to have a meaningful impact.[15] This is the first paper to describe the participatory, co-development process of an ERS for individuals with health conditions. As the co-developed intervention was informed by both scientific evidence and local stakeholder needs, it has potential to improve implementation success and thus, clinical effectiveness. This study has important

applicability to wider public health settings, where there is a need for cost-effective interventions that are feasible to implement in practice. Sequential research is needed to implement and evaluate co-developed interventions to determine effectiveness.

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Table Titles

Table 1. Summary of development meeting content collected between April and August 2016 in Liverpool, UK.

Table 2. Summary of pragmatic facilitators and challenges of a participatory research process (April-August 2016, Liverpool, UK)

Figure Legends

Figure 1. Flow diagram of a preliminary intervention framework for a PA referral scheme, co-developed from participatory meetings 1 and 2 (April 2016, Liverpool, UK). The framework was underpinned by the identified importance of focussing on PA and incorporating behaviour change support, the involvement of a Health Trainer service, and solving accountability concerns (i.e. ERP assessments pre- and post-intervention).

Figure 2. Overview of the PA referral scheme framework co-developed between April and August 2016 in Liverpool, UK. Fundamental adaptations from the existing scheme in operation were: a unified focus on lifestyle PA and not 'just structured exercise' per se; additional consultations at week 4 and week 18; structured behaviour change support delivered by ERPs; optional supplementary support from a Health Trainer service for additional health behaviours (e.g. nutrition, smoking, alcohol etc.); and collection of patient-determined evaluation data (e.g. PA, psychological wellbeing, body mass). The target population will be inactive individuals with health-related risk factors or conditions aligned with NICE recommendations [34]. Behaviour change consultations will be underpinned by Self-Determination Theory [29] and will include a range of behaviour change techniques.