Community-based intervention to promote physical activity in rheumatoid arthritis (CIPPA-RA): a study protocol for a pilot randomised control trial

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Abstract

Background

Physical activity is an important aspect in the management of rheumatoid arthritis (RA), a chronic inflammatory condition which impacts physical and mental health outcomes in this population. Interventions targeting physical activity behaviour in people who have RA have had limited efficacy and little integration of behaviour change theory. This paper describes the development of an intervention to promote physical activity in people with RA, integrating the Theory of Planned Behaviour (TPB), Behaviour Change Wheel (BCW) and the UK Medical Research Council guidance on complex interventions.

Methods

The BCW, a narrative review and a systematic review were utilised to guide selection of target behaviour. Two qualitative studies were then conducted with key stakeholders to further inform intervention development. This information linked with the constructs of TPB and assisted in determining the intervention functions, behavioural change techniques and implementation strategy anticipated to have the most effective behavioural change.

Results

Two target behaviours were identified – moderate intensity physical activity behaviour in people who have RA and supporting physical activity by health professionals (HPs). Education, enablement and modelling intervention functions, aligning with the constructs of attitudes and perceived behavioural control (PBC) were identified for people who have RA. Information about health consequences, instruction on how to perform a behaviour, goal setting, action planning, review of behaviour goals and self-monitoring of behaviour were selected as techniques. Education, training and enablement were identified functions. Instruction on how to perform behaviour and information about health consequences were selected as the most appropriate behaviour change techniques. A credible source was identified as being essential.

Conclusions

This is a novel intervention proposal as it integrates the TPB and the BCW framework with the MRC guidance on complex interventions. As each stage of the development process is clearly described, it will allow for evaluation of effective ness and ensures that replication and improvement of the intervention can be facilitated.

Background

RA is a chronic inflammatory condition which affects 0.5% of the adult population worldwide (1). It occurs in 20–50 cases per 100 000 annually, most commonly in women (1). RA is characterised by joint swelling, joint tenderness, and destruction of synovial joints (2). Cardiovascular disease (CVD), infections or lymphoma occur more frequently in people who have RA and this population has increased mortality rates compared with the general population (1). Symptoms such as pain and fatigue are prevalent in the disease (3) with mental health issues such as depression and anxiety (4) impacting people who have RA.

Physical activity is an important aspect in the management of RA. It has been highlighted as an essential component in reducing the risk of CVD (5), and is known to reduce the symptoms associated with this condition and to improve quality of life (6-7). People who have RA do not participate in sufficient physical activity to obtain the many health benefits that are associated with being physically active at recommended levels (8-10). Interventions which have targeted physical activity behaviour in people who have RA have had limited success in increasing and maintaining physical activity behaviour change in the longer term (11-12). Low physical activity levels has been shown to be an independent risk factor for number of hospital admissions and duration of hospitalisation in people who have RA (13). Thus by increasing the levels of physical activity in people who have RA it may serve to reduce healthcare costs and enhance the health outcomes of the RA population.

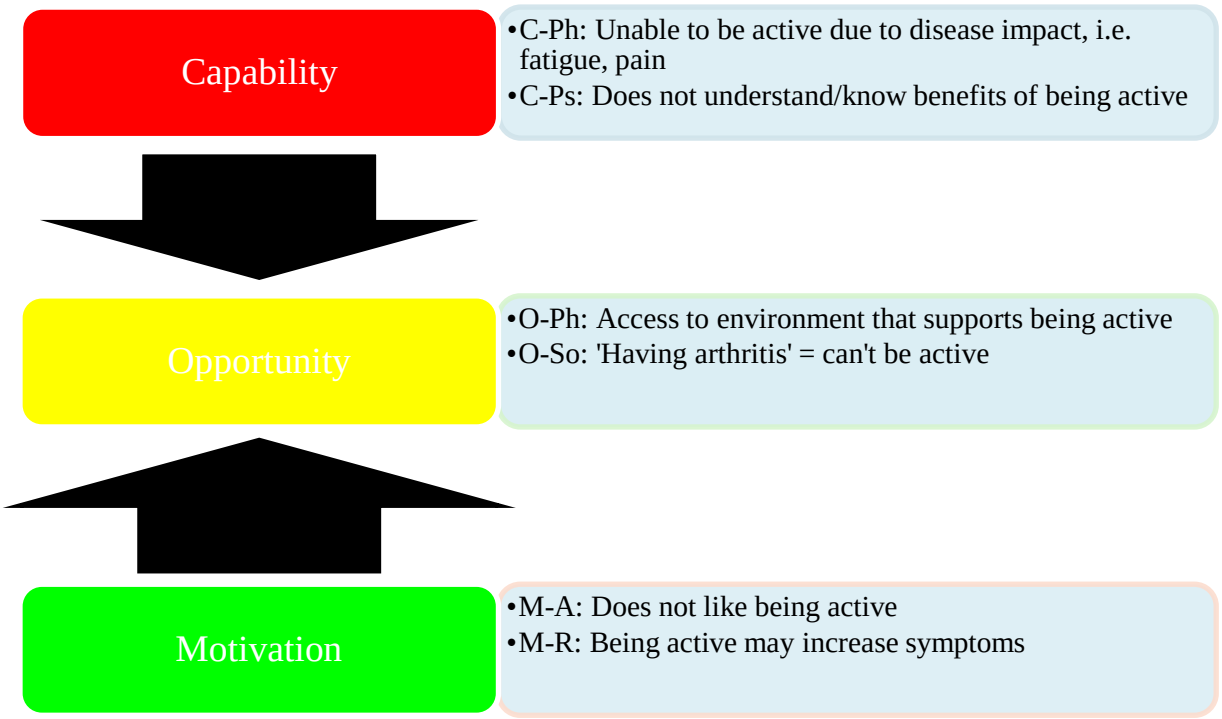
Interventions which target behaviour change often include numerous interacting components and such interventions are known as complex interventions (14). The need for numerous interacting components stems from the fact that behaviour can be influenced by many factors, for example personal, social, practical and contextual factors (15). Due to interactions between numerous components complex interventions often present a number of problems for evaluators, in addition to the practical and methodological difficulties that any successful evaluation must overcome (14). For example lack of consideration of the local context can provide a barrier to intervention delivery, implementation or evaluation (14) thus consultation of key stakeholders is essential when developing an intervention targeting behaviour change (14, 16). By consulting with people who have RA when developing an intervention it can help to ensure that the proposed research is appropriate and acceptable for the patient population (17). Equally consulting health professionals (HPs) who may be involved in the delivery of an intervention can identify potential challenges and/or facilitators to a

proposed intervention and allows for consideration of such factors when designing an intervention (18-19).

A sound theoretical underpinning is essential in complex interventions in understanding how the intervention causes change, so that weak links in the causal chain can be identified and strengthened (14). To date interventions which have targeted physical activity behaviour change in people who have RA have lacked this theoretical understanding (20-21). This poses a challenge when seeking to improve upon the design of previous interventions which targeted physical activity behaviour, as the effective components and how change came about within an intervention cannot be identified. The correct and appropriate use of theory and its measurement can facilitate behavioural analysis of the controlling antecedents and consequences of implementation which may help develop effective interventions (22).

By designing an intervention which is guided by a strong theoretical underpinning and by selecting behaviour change techniques which are appropriate to influence behaviour change it is envisaged that this novel intervention proposal will extend on the previous research within this field. Seeking to select one specific behaviour change theory can be challenging as some are poorly developed or may not acknowledge key factors which may influence behaviour change (23). Thus adopting the Behaviour Change Wheel (BCW), a theoretical framework which explicitly integrates behavioural theory with the development and description of behavioural change interventions (24), is warranted. The BCW model is based on the interactions between one's capability (C), opportunity (O) and motivation (M) and can provide explanations as to why a particular behaviour (B) is or is not performed (COM-B). Each of these components can be further subdivided (Figure 1).

Figure 1: The COM-B Model: Behaviour: Physical activity in people who have RA



This paper describes the development of an intervention to promote physical activity in people who have RA. The Theory of Planned Behaviour (TPB) (25) was identified as the most appropriate theory to underpin the intervention development, as it acknowledges the influence of attitude, subjective norm and degree of perceived behavioural control (PBC) on behaviour (20). The steps of the BCW were applied to enable a more transparent implementation of the UK Medical Research Council (MRC) framework for design and evaluation of complex interventions (14, 24).

Methods

MRC stage 1: identifying the evidence base

To identify the current evidence the available literature on physical activity in people have RA was reviewed and supplemented with new evidence to ensure that the problem was clearly defined and facilitated selection of the specific behaviour for the proposed intervention.

Behaviour Change Wheel step 1: define the problem in behavioural terms

As described earlier people who have RA have poorer health outcomes which can be positively impacted by physical activity. The research team have conducted extensive research in the area of RA and were familiar with the large body of research which

highlighted the low levels of physical activity in people who have RA (8, 10. 26-27). To enhance this knowledge two reviews were conducted – a narrative review (20) and a systematic review (21). The narrative review explored common behaviour change theories and examined how such theory had been utilised in the area of behaviour change for physical activity in people who have RA. The systematic review incorporated papers which had sought to promote physical activity in people who have RA and examined the structure, delivery mode and content of these interventions. The types of behaviour change techniques which had been employed was also explored and categorised as per the Behaviour Change Taxonomy (15).

Behaviour Change Wheel step 2: select the target behaviour

Given the evidence base that supports physical activity as an important aspect of disease management in the RA population (5) the research team identified this as the target behaviour of the proposed behaviour change intervention.

Behaviour Change Wheel step 3: specify the target behaviour

Physical activity is a complex and multidimensional behaviour which encapsulates many elements and domains (28). Physical activity can be categorised in many ways, i.e. by domain (leisure-time physical activity, work- or school-related activity; household, domestic, self-care activities, transport) (28), by type (aerobic, muscle-strengthening, flexibility) or intensity (low, moderate or high intensity). Thus specifying which aspect of physical activity behaviour to target can prove challenging. Moderate intensity exercise involves being active with a heart rate of 50-74% of maximal heart rate or 3-6 metabolic equivalents (29), and demonstrates significant health benefits in people who have RA (30). The research team selected moderate intensity aerobic physical activity as the target behaviour, i.e. to meet current guidelines of 150 minutes per week (29).

MRC stage 2: identifying/developing theory

In stage 2 of the MRC framework the TPB and COM-B (capability, opportunity, motivation—behaviour) model (Figure 1) were considered to develop a theoretical understanding of the target behaviour and guide choice of intervention functions. A central factor in the TPB is the individual's intention to perform in a given behaviour. Intentions are assumed to capture the motivational factors that influence a behaviour. The TPB involves the constructs of attitude, subjective norm and degree of PBC, which facilitated an explicit theoretical underpinning in this stage of development. Attitude is informed by beliefs about physical activity and the expected outcomes of being

physically active. Subjective norm is informed by beliefs that significant others hold and the motivation to comply with others. PBC is informed by control variables and power over control factors (25).

Behaviour Change Wheel step 4: identify what needs to change to achieve the desired behaviour

It was evident that the interventions conducted to date had not involved key stakeholders when seeking to design the behaviour change intervention (20-21). The MRC (14) advocates the involvement of key stakeholders when designing complex interventions and so to compliment the quantitative reviews in stage 1 of the MRC qualitative interviews with people who have RA and HPs who work in rheumatology were conducted. This highlighted some elements which needed to change to achieve increased moderate intensity aerobic physical activity behaviour in people who have RA.

Behaviour Change Wheel step 5: identify intervention functions to achieve the desired behaviour

The BCW includes a panel of nine intervention functions (Table 1) which were devised from a synthesis of 19 frameworks of behavioural intervention strategies (31). The term 'intervention function' is used as any particular intervention strategy may have more than one function (24). The COM-B components were mapped to the BCW linkage matrices and intervention functions that were most likely to influence behavioural change within our context were selected (Table 2). The Theoretical Domains Framework which is an integrative framework synthesising key theoretical constructs used in relevant theories was also considered (32). The Theoretical Domains Framework consists of 14 domains; knowledge; skills; memory, attention and decision processes; behavioural regulation; social/professional role and identity; beliefs about capabilities; optimism; beliefs about consequences; intentions; goals; reinforcement; emotion; environmental context and resources; and social influences, and describes the theoretical constructs within each domain. Each domain of the Theoretical Domains Framework relates to a COM-B component (24). Several intervention functions were considered to be relevant for this intervention thus the affordability, practicability, effectiveness and cost effectiveness, acceptability, side effects/safety and equity (APEASE) criteria were employed to assist in ranking the potentially relevant intervention functions (24). The APEASE criteria acknowledges that behaviour change interventions operate within a social context, and that although effectiveness is the

primary focus of interventions it is clearly important to consider other contextual factors (24).

Table 1: Intervention functions

Function	Description
Education	Increasing knowledge or understanding (what to do and why)
Persuasion	Using communication to induce positive or negative feelings or stimulate action
Incentivisation	Creating an expectation of reward
Coercion	Creating an expectation of punishment or cost
Training	Imparting skills (how to do something)
Restriction	Using rules to reduce opportunities to engage in the target behaviour
Environmental restructuring	Changing the physical or social context
Modeling	Providing an example for people to aspire to or imitate
Enablement	Increasing means/reducing barriers to increase capability (beyond education or training) or opportunity (beyond environmental restructuring)

Behaviour Change Wheel step 6: policy categories

The BCW includes elements which indicate the seven broad policy-level interventions for achieving behavioural change. Changing policy was not a primary aim of this project however some options that may be relevant in this context in the future are suggested.

Table 2: Selecting appropriate intervention functions: Linking with COM-B components

MRC stage 3: modelling process and outcomes

This stage of the development process sought to determine the intervention content in greater detail and considered the contextual challenges/facilitators that would help to ensure the design of an intervention that aims not only to be effective but also appropriate within our context. The relevant constructs of the TPB and how to target these constructs using motivational and/or volitional strategies were also considered. Specific behaviour change techniques were identified as per the Behaviour Change Taxonomy to address either motivational or volitional strategies.

Behaviour Change Wheel step 7: identify behavioural change techniques

Having selected suitable interventions functions in *BCW step 5* the behaviour change taxonomy, which consists of 93 behaviour change techniques, was examined (15) to identify behaviour change techniques which were used most often within the selected intervention functions. A meeting between the research team was conducted to review the appropriateness of each behaviour change technique in relation to targeting the TPB constructs. The meeting included reflection on the developmental quantitative and qualitative data, the context of the intervention and consideration of the APEASE criteria. Each member of the research team had expertise in one or more areas of relevance, namely physical activity (LL, NK), RA (AF, NK, LL), behavioural science and intervention design (SG, LL) and the public healthcare system (AF, LL).

Behaviour Change Wheel step 8: identify mode of delivery

It was envisaged that the intervention would be delivered in a community setting, given the strain on acute hospital services within the Irish healthcare setting and also due to the emphasis on care delivery within a community setting (33). Given that primary care services have developed at a slower rate than anticipated and can vary depending on geographical location the research team were conscious of these factors when determining the appropriate mode of delivery. The MRC framework poses specific modelling questions relevant to this step, which include would it be possible to use this, what group of patients should it be used for, what outcomes should be sought and what are the facilitators/obstacles at practice level (14).

Results

The process of developing this intervention is outlined in Table 3, and shows how the steps of the BCW (24) were mapped to the UK MRC's guide on complex interventions in healthcare (14).

>>>>Table 3 Goes Here<<<<<<<<

MRC stage 1: identifying the evidence base

BCW step 1: define the problem in behavioural terms

Two reviews were conducted to determine what the problem was in promoting physical activity behaviour in people who have RA. Larkin *et al.* (20) was a narrative review which examined four studies which sought to promote physical activity in people who have RA. The review demonstrated two key points; (i) too often theory is not an integral part of intervention design and development and (ii) that there has been limited success in the efficacy of theory-based interventions to increase and maintain physical activity behaviour in people who have RA. The TPB was suggested as the appropriate theory to underpin intervention development, as it had not been previously applied in people who have RA in relation to physical activity behaviour. A systematic review was conducted, with five original studies being included. Larkin *et al.*(21) highlighted that a small number of studies (n=3) reported short term increases in physical activity behaviour, with only one study demonstrating maintenance in physical activity behaviour at long-term follow-up. A wide variety of behaviour change techniques were employed, however selection of techniques and the methods in how each technique was implemented was poorly described. Interestingly the studies which were effective in promoting physical activity behaviour (12; 34-35) used similar behaviour change techniques to the studies that did not demonstrate an improvement in physical activity behaviour. This suggests that differences in the content, structure and delivery of each behaviour change intervention may potentially account for the variation in effectiveness of behaviour change interventions to date.

Behaviour Change Wheel step 2: select the target behaviour

The research team considered when seeking to change behaviour within a healthcare context there are two key people; (i) the person who has RA, (ii) the HP (or other individual) working with that person. Thus, there was a need to incorporate the behaviours of both groups of people in seeking to develop an effective behaviour change intervention.

Behaviour Change Wheel step 3: specify the target behaviour

Based on the above information two key behaviours were identified; (i) for people who have RA to increase their moderate intensity aerobic physical activity levels, (ii) for HPs (other individuals) to support people who have RA to become physically active (and/or maintain current physical activity behaviour).

MRC stage 2: identifying/developing theory

Behaviour Change Wheel step 4: identify what needs to change to achieve the desired behaviour

The qualitative studies conducted with people who have RA and HPs complimented the findings of the reviews described in *Step 1*. The interviews with people who have RA (36) demonstrated a lack of knowledge and information regarding physical activity recommendations and a fear that being physically active would increase the symptoms of RA. These findings related primarily to the constructs of attitudes and PBC in the TPB. The COM-B model was used to map these findings to the BCW theoretical framework (Table 4). The lack of knowledge and information about physical activity was mapped to Capability-Psychological. Fears of increasing symptoms were mapped to Motivation-Reflective and beliefs that having RA can limit physical activity were mapped to Opportunity-Social. The qualitative study conducted with HPs working in rheumatology (37) found HPs had varying views on when and how active people who have RA should be, highlighting a lack of knowledge of current recommendations for physical activity in people who have RA and a lack of available training to update this knowledge. Linking these findings to the TPB constructs indicated that attitude is an important construct in the behaviour of HPs in this context, and also mapped to Capability-Psychological in the COM-B model. The HPs described using strategies to promote and support physical activity behaviour in people who have RA, which reflected behaviour change techniques such as goal setting, monitoring physical activity, modelling of behaviour and information from a credible source. In addition, the HPs discussed contextual factors, for example limited time, which were considered under *Step 8* of the BCW framework.

Table 4: Understanding the behaviour: Selecting appropriate behaviour functions

Barriers identified from qualitative research with people who have RA (Larkin *et al.* 2016b)	Barriers identified from qualitative research with health professionals (Larkin *et al.* 2016a)	COM-B components
•Lack of knowledge •Lack of information	•Lack of knowledge •Lack of training	Capability - Psychological
•Fear of increasing symptoms		Motivation - Reflective
•Beliefs that having RA limits ability		Opportunity - Social

RA = Rheumatoid arthritis

Behaviour Change Wheel step 5: identify intervention functions to achieve the desired behaviour

For the behaviour of people who have RA to increase/maintain their levels of general moderate intensity aerobic physical activity all intervention functions were relevant and identified as being suitable (Table 5). The APEASE criteria (24) were used to guide ranking of intervention functions, resulting in the selection of education, enablement and modelling. These intervention functions aligned with targeting the constructs of attitudes and PBC. For the behaviour of HPs to support people who have RA to increase/maintain physical activity behaviour the intervention functions of education, training and enablement were identified. Based on the APEASE criteria (24) the functions were ranked in the order of education, training and enablement, aligning with the attitudes construct in the TPB.

Table 5: Selecting intervention functions: APEASE criteria

BCW intervention functions	Affordability	Practicability	Effectiveness and cost effectiveness	Acceptability	Side effects/safety	Equity	Decision Yes/No
Education	✓	✓	✓	✓	✓	✓	**Yes: People who have RA and HPs**
Persuasion	✓	✓	✓	✓	✓	✓	No
Incentivisation	✓	×	✓	×	×	✓	No
Coercion	✓	×	✓	×	×	✓	No
Training	✓	✓	✓	✓	✓	✓	**Yes: HPs**
Restriction	✓	×	✓	×	×	✓	No
Environmental restructuring		×	✓	×	✓	✓	No
Modelling	✓	✓	✓	✓	✓	✓	**Yes: People who have RA**
Enablement	✓	✓	✓	✓	✓	✓	**Yes: People who have RA** **No: HPs**

BCW = Behaviour Change Wheel; RA = Rheumatoid arthritis; HPs = Health professionals

Behaviour Change Wheel step 6: policy categories

The policy categories that may facilitate behaviour change on a larger scale include guidelines, service provision and communication/marketing and are useful for consideration in future research.

MRC stage 3: modelling process and outcomes

Behaviour Change Wheel step 7: identify behavioural change techniques

Considering the constructs of the TPB the behaviour change taxonomy of 93 behaviour change techniques (31) was used to select techniques that would target the theoretical constructs and serve the intervention functions identified. A large range of techniques for both people who have RA and HPs were selected (Table 6). Each technique was discussed at a meeting of the research team, who reached a consensus on which behaviour change techniques were most suitable for the context and relevant theoretical constructs. For people who have RA the techniques selected were information about health consequences (motivational strategy), instruction on how to perform a behaviour, goal setting, action planning, review of behaviour goals and self-monitoring of behaviour (volitional strategies). Importantly some of the techniques were described by both people who have RA and HPs as strategies that would support physical activity behaviour, for example goal setting (36-37). All of the aforementioned techniques were to be delivered by a credible source, i.e. a person who has RA or a HP. For HPs instruction on how to perform behaviour (volitional strategy) and information about health consequences (motivational strategy) were selected as the most appropriate behaviour change techniques. The techniques selected were to be delivered from a credible source such a member of the research team who is up to date with research in the area of physical activity in RA.

Table 6: Linking intervention functions with behaviour change techniques

Intervention function	Most frequently used behaviour change techniques
Education	➢ 5.3 Information about social and environmental consequences ➢ 5.1 Information about health consequences ➢ 2.2 Feedback on behaviour ➢ 2.7 Feedback on outcome(s) of behaviour ➢ 7.1 Prompts/cues ➢ 2.3 Self-monitoring of behaviour
Enablement	➢ 6.1 Demonstration of behaviour
Modeling	➢ 3.1 Social support (unspecified) ➢ 3.2 Social support (practical) ➢ 1.1 Goal setting (behaviour) ➢ 1.3 Goal setting (outcome) ➢ 12.5 Adding objects to the environment ➢ 1.2 Problem solving ➢ 1.4 Action planning ➢ 2.3 Self-monitoring of behaviour ➢ 12.1 Restructuring the physical environment ➢ 1.5 Review behaviour goal(s) ➢ 1.7 Review outcome goal(s)
Training	➢ 6.1 Demonstration of behaviour ➢ 4.1 Instruction on how to perform a behaviour ➢ 2.2 Feedback on behaviour ➢ 2.7 Feedback on outcome(s) of behaviour ➢ 2.3 Self-monitoring of behaviour ➢ 8.1 Behavioural practice/rehearsal

Behaviour Change Wheel step 8: identify mode of delivery

The questions outlined in *BCW step 8* and how best the interventions could be delivered were considered. It possible to deliver interventions targeting the behaviour of people who have RA and HPs to increase moderate intensity aerobic physical activity levels. The group of people who were identified as being most suitable for this intervention were people who have RA that currently do not meet the recommendations for moderate intensity aerobic physical activity which is 150 minutes per week (29), which is known to be beneficial and safe for people who have RA (38). The outcomes of the intervention for people who have RA should measure change in physical activity behaviour, changes in symptoms, and change in beliefs regarding physical activity behaviour. The latter should also be measured in HPs. Measuring the aforementioned outcomes will assist in further identifying factors which may influence behaviour change in these specific populations.

In considering the potential modes of delivery (24) the research team reflected on the findings of the qualitative research which highlighted important points when seeking to deliver an intervention in a clinical practice setting. The APEASE criteria were applied to guide the research team's selections, as outlined in Tables 7 and 8 (24). Both people who have RA and HPs were in favour of an intervention being delivered in a community setting for people who have RA. For mode of delivery both face-to-face and remote/web-based interventions were considered. Face-to-face interventions and remote/web-based interventions have been reported to be effective in promoting physical activity (39-40). Other aspects of determining if an intervention should be delivered face-to-face or remote/web-based, such as cost effectiveness, have yet to be determined (39-40) thus the research team gave strong consideration to the findings of the reviews and qualitative studies conducted. Given the strong body of evidence which indicates that people who have RA value information and advice from a credible source, namely their rheumatologist or other HPs (36; 41-42) , the research team selected a face-to-face intervention as the most appropriate mode of delivery. There were varied views on whether interventions should be individual or group-based for people who have RA. Delivering a face-to-face intervention is challenging when there is a lack of resources in clinical practice, e.g. time, staffing. Thus a group-based approach, delivered over three sessions and based in a community location, was considered as feasible within the Irish healthcare setting. This should facilitate appropriate intervention and follow-up, as well as objective behaviour monitoring. For HPs a distance-based intervention was identified as being most practical as it accounted for the lack of time highlighted by HPs in the qualitative research.

Table 7: Selecting mode of delivery – people who have RA: APEASE criteria

Mode of delivery	Affordability	Practicability	Effectiveness and cost effectiveness	Acceptability	Side effects/safety	Equity	Decision Yes/No
Face-to-face: individual	✓	✓	✓	✓	✓	✓	No
Face-to-face: group	✓	✓	✓	✓	✓	✓	**Yes**

Table 8: Selecting mode of delivery – HPs: APEASE criteria

Mode of delivery	Affordability	Practicability	Effectiveness and cost effectiveness	Acceptability	Side effects/safety	Equity	Decision Yes/No
Face-to-face: group	✓	×	✓	×	✓	✓	No
Distance: population level → digital media → internet	✓	✓	✓	✓	✓	✓	**Yes**

Discussion

This paper describes the systematic, structured development of an intervention to promote physical activity in people who have RA. The intervention will consist of two strands, one targeting the behaviour of people who have RA and the other targeting the behaviour of HPs in promoting physical activity in this population. This is the first proposed intervention targeting the promotion of physical activity behaviour in a clinical setting developed with the TPB as its' theoretical underpinning and by using the BCW to clearly implement the framework of the MRC guide on complex interventions.

When setting out to design the intervention it was anticipated that the behaviour of people who have RA would be the primary focus of the proposed intervention. However having reviewed the evidence base and conducting original research we determined that addressing the behaviour of HPs who work with people who have RA was an equally important aspect when seeking to promote the levels of moderate intensity aerobic physical activity in people who have RA. The intervention functions selected for people who have RA (education, enablement and modelling) and HPs (education and training) were used to guide the selection of behaviour change techniques. To ensure that the intervention was theoretically informed the research team considered the selection of behaviour change techniques that would target constructs of the TPB but that were also deemed appropriate for the context of the proposed intervention. A common link between the proposed behaviour change techniques for people who have RA and HPs is that the intervention will be delivered from a credible source (41, 42) . Furthermore as the education and training provided to HPs will be from the research team who are familiar with the most recent evidence on physical activity in people who have RA it will serve the high value that HPs have on evidence-based practice in a clinical setting.

Strengths and weaknesses

The aim of this paper was to develop an intervention to promote physical activity behaviour in people who have RA. The MRC framework (14) for complex interventions guided the development of the project. This assisted in ensuring that the different strands of developing the proposed intervention followed a logical structure and consisted of research which identified the evidence base and current theory in physical activity promotion in people who have RA and the modelling of process and outcomes of the proposed intervention.

A strength of this paper is that it provides a comprehensive view of how the proposed intervention was developed. As outlined by the MRC framework (14) the evidence base was identified by

conducting a systematic review. This was supplemented with a review of theory and its' use in behaviour change interventions in people who have RA. This research was expanded upon by conducting qualitative research with key stakeholders in the intervention, which provided a new insight into the preferences of both people who have RA and HPs, and directly influenced the design of the proposed intervention. Using the TPB as the theory underpinning this development and by considering the BCW as a guiding theoretical framework it facilitated linking theoretical constructs with appropriate behaviour change techniques. This allows for clear replication and revision of the intervention as required. The use of the BCW has broadened our consideration of potential behaviour change options, some of which we may not have considered without the guidance of the BCW and the behaviour change techniques taxonomy. Having to consider all potential options ensured that the functions and behaviour change techniques selected are well grounded in the developmental work and well justified.

The TPB is an attitude-based theory, which related to the constructs known to influence behaviour in people who have RA. Criticisms of the TPB have been outlined elsewhere (20); however the TPB has not been applied previously in this population. The BCW is a valuable framework for designing behaviour change interventions, but challenges remain for the researcher, e.g. considering how a behaviour change intervention could be feasibly delivered within a clinical setting. To account for such issues we sought to combine research findings with knowledge of local factors when designing the intervention, and have attempted to detail such considerations in depth for the purpose of clarity and comprehensiveness.

Developing an intervention of this nature has been a lengthy process. This project has been developed over the course of three years due to its' multi-faceted nature. However, the depth and breadth of the research over this prolonged period of time has resulted in the proposal of an intervention which is logical, practical and importantly has a clear theoretical basis. To determine if the intervention proposed is acceptable to the key stakeholders and to allow for further refinement of the specific intervention detail, i.e. specific outcome measures, participant numbers, geographical location of delivery and other such factors, there is a need for further work on the project. This additional work may alter or re-shape the proposed intervention; however having used the BCW allows for ease of refinement and replication, and should result in an intervention that is acceptable and feasible when seeking to promote physical activity behaviour in people who have RA.

Implications for future research and clinical practice

The development process of this intervention has highlighted some important issues with regard to both people who have RA and HPs. For people who have RA there is an apparent lack of knowledge regarding their chronic condition. Increased provision of information at the time of diagnosis within the acute rheumatology setting may be warranted to address this issue. For HPs there is an apparent lack of knowledge of recent evidence on physical activity for people who have RA. Future research will explore the acceptability of the proposed HP behaviour change intervention which will aim to address this gap. This finding points to a lack of training or focus on rheumatology within the education of future HPs at university level. There is also a need increase the training of HPs regarding behaviour change, given the demands of addressing lifestyle factors within clinical practice.

Conclusion

The intervention proposed is novel in that it integrates the TPB and the BCW framework with the MRC guidance on complex interventions. Although this is by no means claiming to be the perfect intervention the fact that each stage of the development process is clearly described ensures that replication and improvement of the intervention can be facilitated.

Declarations

Abbreviations

BCW: Behaviour change wheel; COM-B: capability, opportunity, motivation, behaviour; HP(s): Health professional(s); MRC: Medical Research Council; PBC: perceived behavioural control; RA: Rheumatoid arthritis; TPB: Theory of Planned Behaviour

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

LL designed the study, conducted data analysis and wrote initial draft of the paper. NK, SG and AF contributed to study design, data analysis, judgements on intervention design and revising the manuscript.

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Table 3: Mapping steps of Behaviour Change Wheel to the three stages of intervention development in the UK Medical Research Council guide on complex interventions in healthcare

MRC development stage (14)	Behaviour Change Wheel steps (including TPB) (24)	Behaviour Change Wheel stages
1. Identify the evidence base ➢ Systematic review (21) ➢ Narrative review (20)	1. Define the problem in behavioural terms ➢ Poor health outcomes in people who have RA, e.g. increased CVD 2. Select the target behaviour ➢ Physical activity 3. Specify the target behaviour ➢ Increase moderate intensity physical activity levels	1. Understand the behaviour
2. Identify/develop theory ➢ TPB ➢ COM-B	4. Identify what needs to change **People who have RA (36)** ➢ Knowledge of physical activity recommendations for people who have RA (attitude) ➢ Beliefs about being active with RA (attitude; PBC) **HPs (37)** ➢ Knowledge of physical activity recommendations for people who have RA (attitude)	
	5. Identify appropriate intervention functions/theoretical strategies **People who have RA** ➢ Education ➢ Enablement ➢ Modeling **HPs** ➢ Education ➢ Training	2. Identify intervention options
	6. Identifying policy categories ➢ Not addressed in current study but future options to be considered **People who have RA** ➢ Communication/Marketing	

MRC development stage (14)	Behaviour Change Wheel steps (including TPB) (24)	Behaviour Change Wheel stages
	HPs ➢ Guidelines ➢ Service provision	
3. Model process and outcomes ➢ Intervention content ➢ Implementing intervention within our context	7. Identifying behavioural change techniques (linked with TPB strategies) **People who have RA** ➢ 1.1 Goal setting (behaviour) ➢ 1.2 Problem solving ➢ 1.4 Action planning ➢ 1.5 Review behaviour goals ➢ 2.2 Feedback on behaviour ➢ 2.3 Self-monitoring of behaviour ➢ 4.1 Instruction on how to perform a behaviour ➢ 5.1 Information about health consequences ➢ 5.2 Salience of consequences ➢ 5.3 Information about social and environmental consequences ➢ 6.1 Demonstration of behaviour ➢ 6.2 Social comparison ➢ 8.1 Behavioural practice/rehearsal ➢ 9.1 Credible source **HPs** ➢ 4.1 Instruction on how to perform behaviour ➢ 5.1 Information about health consequences ➢ 6.1 Demonstration of behaviour ➢ 6.2 Social comparison ➢ 9.1 Credible source 8. Determine the mode of delivery **People who have RA** ➢ Once-off face-to-face session delivered by HPs in community setting ➢ **HPs** ➢ Online educational resource, e.g. website, short course	3. Identify content and implementation options

MRC development stage (14)	Behaviour Change Wheel steps (including TPB) (24)	Behaviour Change Wheel stages

MRC = Medical Research Council; TPB = Theory of Planned Behaviour; COM-B = Capability, Opportunity, Motivation – Behaviour; CVD = Cardiovascular disease; PBC = Perceived Behavioural Control; RA = Rheumatoid arthritis; HPs = Health professionals