

1 **Title: Using intervention mapping to develop a theory driven, group-based complex intervention**
2 **to support self-management of osteoarthritis and low back pain (SOLAS)**

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4 Deirdre A Hurley^{1*}, Laura Currie Murphy², David Hayes³, Amanda M Hall⁴, Elaine Toomey⁵, Suzanne
5 M McDonough⁶, Chris Lonsdale⁷, Nicola E Walsh⁸, Suzanne Guerin⁹, James Matthews¹⁰

6 1. Deirdre A Hurley, UCD School of Public Health, Physiotherapy and Sports Science, University
7 College Dublin, Dublin 4, Ireland deirdre.hurleyosing@ucd.ie

8 2. Laura Currie-Murphy, Breast-Predict - Collaborative Cancer Research Centre, Pharmacology
9 and Therapeutics, Trinity College Dublin, St James's Hospital, Dublin 8, Ireland.

10 Laura.Murphy@tcd.ie

11 3. David Hayes, UCD School of Psychology, University College Dublin, Dublin 4, Ireland.

12 david.hayes@ucdconnect.ie

13 4. Amanda M Hall, The George Institute for Global Health, Oxford Martin School, Oxford
14 University, United Kingdom. amanda.hall@georgeinstitute.ox.ac.uk

15 5. Elaine Toomey, UCD School of Public Health, Physiotherapy and Sports Science, University
16 College Dublin, Dublin 4, Ireland. elaine.toomey@ucdconnect.ie

17 6. Suzanne McDonough, Institute of Nursing and Health Research, Ulster University,
18 Jordanstown Campus, Antrim, BT37 0QB, Northern Ireland. s.mcdonough@ulster.ac.uk

19 7. Chris Lonsdale, Institute for Positive Psychology and Education, Faculty of Health Sciences,
20 Australian Catholic University, 25A Barker Road, Strathfield NSW 2135, Australia.

21 Chris.Lonsdale@acu.edu.au

22 8. Nicola E Walsh, Faculty of Health and Applied Sciences, University of the West of England,
23 Glenside Campus, Bristol, BS16 1DD, United Kingdom. nicola.walsh@uwe.ac.uk

1 9. Suzanne Guerin, UCD School of Psychology, University College Dublin, Dublin 4, Ireland.
2 suzanne.guerin@ucd.ie

3 10. James Matthews, Institute for Sport and Health, UCD School of Public Health, Physiotherapy
4 and Sports Science, University College Dublin, Dublin 4, Ireland. james.matthews@ucd.ie

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7 *Corresponding author

1 **Abstract**

2

3 **Background:** The Medical Research Council framework provides a useful general approach to
4 designing and evaluating complex interventions, but does not provide detailed guidance on how to
5 do this and there is little evidence of how this framework is applied in practice. This study describes
6 the use of intervention mapping (IM) in the design of a theory driven, group-based complex
7 intervention to support self-management (SM) of patients with osteoarthritis (OA) and chronic low
8 back pain (CLBP) in Ireland’s primary care health system.

9 **Methods:** The six steps of the IM protocol were systematically applied to develop the Self-
10 management of Osteoarthritis and Low back pain through Activity and Skills (SOLAS) intervention
11 through adaptation of the Facilitating Activity and Self-management in Arthritis (FASA) intervention.
12 A needs assessment including literature reviews, interviews with patients and physiotherapists, and
13 resource evaluation was completed to identify the programme goals, determinants of SM behaviour,
14 consolidated definition of SM, and required adaptations to FASA to meet health service and patient
15 needs and the evidence. The resultant SOLAS intervention behavioural outcomes, performance and
16 change objectives were specified and practical application methods selected, followed by organised
17 programme, adoption, implementation and evaluation plans underpinned by behaviour change
18 theory.

19 **Results:** The SOLAS intervention consists of six weekly sessions of 90 minutes education and exercise
20 designed to increase participants’ physical activity level and use of evidence-based SM strategies (i.e.
21 pain self-management, pain coping, healthy eating for weight management and specific exercise)
22 through targeting of individual determinants of SM behaviour (knowledge, skills, self-efficacy, fear,
23 catastrophizing, motivation, behavioural regulation), delivered by a trained physiotherapist to
24 groups of up to eight individuals using a needs supportive interpersonal style based on self-
25 determination theory. Strategies to support SOLAS intervention adoption and implementation

1 included a consensus building workshop with physiotherapy stakeholders, development of a
2 physiotherapist training programme and a pilot trial with physiotherapist and patient feedback.

3 **Conclusions:** The SOLAS intervention is currently being evaluated in a cluster randomised controlled
4 feasibility trial. IM is a time intensive collaborative process, but the range of methods and resultant
5 high level of transparency is invaluable and allows replication by future complex intervention and
6 trial developers.

7

8 **Keywords:** Intervention mapping, Complex group intervention, Behaviour change intervention, Self-
9 management, Physical activity, Mixed methods, Physiotherapists, Patient-Public Involvement,
10 Osteoarthritis, Low back pain.

1 **Background**

2 Highly prevalent chronic musculoskeletal pain conditions, such as osteoarthritis (OA) and chronic low
3 back pain (CLBP), place substantial burdens on individuals, health systems, and economies through
4 their profound impact on physical function, psychosocial well-being, quality of life and productivity
5 [1]-[3]. Clinical guidelines endorse patient education about the underlying chronic condition, and
6 support for self-management (SM) behaviours, including physical activity [4]-[7], with SM
7 programmes being championed in many health systems [8]-[10] internationally, but there has been
8 minimal implementation in primary care in Ireland [11]. Contributing factors include variability in
9 how SM is defined in the literature [12], the small effects for interventions in OA [13], the limited
10 evidence base for effective interventions in CLBP [14] management, and the diverse case mix of
11 patients in primary care, which limits the time and expertise [15],[16] of physiotherapists tasked
12 with developing such programmes [17]. Furthermore, the variable quality of Ireland's primary care
13 health system infrastructure and staffing levels present further barriers [11], which taken together
14 have contributed to a 'second translational gap' [18].

15

16 A systematic review of SM interventions for a range of chronic musculoskeletal pain conditions
17 found that short (<8 weeks), healthcare professional delivered, group interventions showed some
18 positive effects, but further research of their effectiveness and cost-effectiveness was warranted
19 [19]. The successful implementation of a standardised, evidence-based clinical and cost effective
20 group programme to support SM for patients with chronic musculoskeletal pain is a key priority for
21 primary care physiotherapy in Ireland [9], however a potential intervention must first be
22 demonstrated to be credible, feasible and implementable within this challenging health service
23 context prior to widespread adoption.

24

25 Complex interventions, for example those designed to improve health outcomes by changing SM
26 behaviour, contain several interacting components, as well as variability within the range of possible

1 outcomes and number of behaviours required by those delivering and receiving the intervention
2 [20]. They typically include behavioural support to improve adherence to the desired behaviour and
3 may target both modifications in healthcare provider behaviour relating to how they interact with
4 patients in delivering the intervention, and patient behaviour in adopting it. Moreover, the causal
5 chain linking a behavioural support intervention to health outcomes is complex and requires a
6 relevant theoretical model to understand its mechanisms of action [21]-[23]. This is further
7 challenged by the demands associated with standardising the design and delivery of the
8 intervention, sensitivity to local context, the organisational and logistical difficulties of applying
9 standard experimental methods and the length and complexity of the causal chains [20]. Indeed, it
10 has been acknowledged that ensuring strict standardisation may be inappropriate and the
11 intervention may work better if a specified degree of adaptation to local settings is allowed [20].
12 Nonetheless, a change in usual clinical practice is often required to ensure successful
13 implementation, notwithstanding the additional complexity of delivering a group intervention [24].

14

15 The Medical Research Council (MRC) updated guidelines recommend an iterative, cyclical phased
16 approach to intervention development and evaluation [20],[25]-[27], noting that “too strong an
17 emphasis on the main evaluation to the neglect of adequate development and piloting or
18 consideration of the practical issues of implementation will result in weaker interventions that are
19 harder to evaluate, less likely to be implemented and less likely to be worth implementing” [20].
20 Concern for implementation should begin in the design phase through consideration of the barriers
21 and enablers to successful implementation and engagement of key stakeholders through
22 involvement in the design and feasibility processes. The MRC framework provides a useful general
23 approach to designing and evaluating complex interventions, but it does not provide detailed
24 guidance on how to do this [28]. While the evaluation phase is widely reported with improving
25 transparency [29], there are few published examples of how the wider aspects of this framework are

1 applied in practice in these populations [30],[31]. Intervention mapping (IM) provides a logical
2 process for intervention development, implementation and evaluation [32] that fulfils the MRC
3 framework criteria and has been previously used to develop [33] and adapt evidence-based SM
4 programmes for other settings [34]. The primary aims of this study were to use the IM process to
5 develop a complex group-based SM intervention (SOLAS: Self-management of Osteoarthritis and
6 Low back pain through Activity and Skills) for Ireland’s primary care physiotherapy service through
7 adaptation of an existing evidence-based programme [Facilitating Activity and Self-management in
8 Arthritis (FASA) [35]] which would serve as a prototype and to address factors related to its
9 implementation in a planned feasibility trial [36] set in the publicly-funded Health Service Executive
10 Primary Community and Continuing Care (PCCC) physiotherapy services of Dublin, Kildare and
11 Wicklow on the east coast of Ireland serving a population of 1.6 million [37].

12

13

14 **Methods**

15 IM is a six step process with each step consisting of several tasks which once completed inform the
16 next step as detailed in Bartholomew et al. [32] and in Figure 1.

17 *Insert Figure 1 approximately here*

18

19 **Step one: needs assessment**

20 The aim of step 1 was to develop programme goals for the intervention related to health and quality
21 of life based on a detailed multi-method assessment of the needs of the PCCC physiotherapy service
22 providers and patients, and the literature regarding SM for chronic musculoskeletal pain to establish
23 how an intervention could be designed to meet these needs.

24

1 **Semi-structured interviews**

2 Individual semi-structured, qualitative interviews were conducted with all consenting physiotherapy
3 managers (n=10) in the catchment area of the feasibility trial and a sample of consenting patients
4 with CLBP and/or spinal OA (n=6) who had recently participated in a group-based physiotherapy
5 programme to understand their needs in relation to a SM intervention. Both studies were approved
6 by the UCD Human Research Ethics Committee-Sciences [Ref no: LS-E-13-103-Hurley-Osing; Ref no:
7 LS-13-25-Toomey-Hurley-Osing]. Deductive thematic analysis based on Braun and Clarke’s method
8 [38] was conducted on the data using the Theoretical Domains Framework (TDF) [39]. The TDF is a
9 validated integrative framework that synthesised key theoretical constructs from 33 behaviour
10 change theories into 14 domains that supports the identification and selection of relevant
11 determinants of behaviour for targeting within interventions. An additional file provides details of
12 the interview topic guides and coding frames [see Additional file 1].

13

14 **Literature reviews**

15 A thematic analysis of chronic disease SM definitions was conducted to reach a consolidated
16 definition. This process is shown in detail in an additional file [see Additional file 2]. This definition
17 was then applied to a rapid review of the effectiveness of physiotherapy delivered group-based SM
18 programmes for OA and CLBP, which was lacking in the literature. An intervention prototype was
19 identified for further adaptation based on its evidence base, similarities in health service context and
20 relevance to the target populations. The most recent international clinical guideline
21 recommendations relating to programme content and SM behaviour for OA and CLBP were
22 reviewed. The behavioural determinants of outcomes of SM interventions identified in recent
23 systematic reviews within the target populations, general behaviour change theories, and behaviour
24 change theories and techniques (BCTs) reported in systematic reviews of SM interventions and our
25 rapid review [40] were reviewed for their relevance to targeting and supporting adherence to SM

1 behaviours [41]. The intervention prototype was then compared to the literature to identify
2 necessary adaptations for SOLAS.

3

4 **Focus groups**

5 Two focus groups with purposively selected consenting physiotherapists (n=28) working in the
6 catchment area were conducted to explore the feasibility of delivering the intervention prototype
7 and the barriers and enablers to be addressed to support intervention implementation and uptake
8 by participants. This study was approved by the UCD Human Research Ethics Committee-Sciences
9 [Ref no: LS-E-13-103-Hurley-Osing]. Deductive thematic analysis based on Braun and Clarke's
10 method [38] was conducted on the data using two coding frames (feasibility and TDF, see Additional
11 file 1). Table 1 shows the operational definitions of feasibility that were used in this study. Proposed
12 changes to the intervention prototype were then addressed during a consensus building workshop
13 outlined in step 4 below.

14

15 *Insert Table 1 approximately here*

16

17 Physiotherapy managers (n=10) completed a resource capacity checklist to identify the practicality
18 of delivering the intervention prototype within their local service settings within the feasibility trial.
19 An additional file shows this process in more detail [see Additional file 3].

20

21 The needs assessment provided the information needed to specify the SOLAS programme goals, the
22 desired SM behaviours it would aim to change within participants and the discrepancies between
23 the selected prototype and the additional content and theoretical underpinnings needed in SOLAS
24 based on the literature and local needs. It also informed the feasibility and necessary modifications
25 to primary care sites to support implementation of SOLAS in the planned trial.

26

1 **Step two: identification of outcomes, performance objectives and change objectives**

2 The behavioural outcomes to be achieved by the SOLAS intervention were developed, and
3 performance objectives [i.e. what a participant has to learn, do or change to achieve the specified
4 outcomes] were stated for each behavioural outcome [32]. Using the information gathered from the
5 needs assessment, the determinants of each behavioural outcome were identified and linked to
6 relevant performance objectives creating a matrix of change objectives that detail what needs to
7 change in the identified determinants to achieve the performance objective.

8

9 **Step three: selecting methods and practical applications**

10 To operationalise the change objectives into practical applications, theoretically informed methods
11 were selected; i.e. each determinant linked to a change objective was mapped to a TDF domain [39],
12 and appropriate intervention methods (i.e. BCTs) were selected. BCTs are intervention components
13 designed to influence the causal determinants that regulate behaviour [42]. This BCT identification
14 process was conducted using appropriate literature [39],[40],[43], extensive discussion by the
15 intervention development group and expert consultation (S Dean, L Atkins). The intervention
16 prototype was reviewed for the specified BCTs, and any omissions were added to SOLAS. The
17 selected BCTs were then converted into practical applications that could be implemented within
18 SOLAS, taking into account the context and environment in which it was being delivered.

19

20 **Step four: creating an organised programme plan**

21 A consensus building workshop was convened with physiotherapy stakeholders (n=6 Managers, 36
22 physiotherapists) working within all 9 PCCC areas for final agreement on the adaptations needed to
23 the intervention prototype structure to devise the SOLAS programme plan, as well as procedures to
24 enhance implementation within the feasibility trial, i.e. physiotherapist training needs. Proposals on
25 which consensus was reached [8/9 PCCC areas voted in favour] were incorporated into the SOLAS

1 intervention design. The definitive intervention content and materials were adapted from the
2 intervention prototype, and relevant additions made.

3

4 **Step five: adoption and implementation plan**

5 The programme use outcomes to achieve successful adoption by physiotherapy managers and
6 implementation by clinical physiotherapists of the SOLAS intervention within the feasibility trial were
7 specified. The determinants of programme adoption and implementation were identified from the
8 TDF analysis of the qualitative studies within the needs assessment and linked to each performance
9 objective to create a matrix of change objectives. The change objectives were converted into
10 practical applications using a range of evidence-based BCTs [43], [44].

11

12 **Step six: creating an evaluation plan**

13 The evaluation plan for SOLAS followed the recommended approach to establish the effect of the
14 intervention on the target SM behaviours within a feasibility trial before moving to a definitive
15 effectiveness trial [21]. This involved the specification of feasibility process and effect evaluation
16 objectives, selection and development of indicators and outcome measures and a comprehensive
17 feasibility trial design including treatment fidelity protocol. All procedures were tested in a pilot trial
18 [UCD Human Research Ethics Committee-Sciences Ref no: LS-13-54-Currie-Hurley] to assess their
19 acceptability and identify further adaptations during the development phase to enhance
20 implementation during the feasibility trial. The pilot trial [April-Aug 2014] was run in four primary
21 care health areas involving eight consenting physiotherapists and 20 consenting participants
22 (12F:8M; mean (SD) age: 59.7 (8.9) years), and included individual semi-structured interviews with a
23 sample of physiotherapists (n=3) and participants (n=5).

24

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26

1 **Results**

2

3 **Step one: needs assessment**

4 The key findings of the multi-method needs assessment are provided below. An additional file shows
5 these results in more detail [see Additional file 4].

6

7 **Semi-structured interviews**

8 The main themes from the manager interviews related to the TDF domains environmental context
9 and resources [i.e. high caseload of patients with CLBP and OA requiring support to self-manage;
10 important role but limited availability of psychologists to contribute to SM programmes], skills [staff
11 experienced in running other groups], intention to support staff to set up group SM programmes and
12 positive beliefs about the consequences of such programmes for patients and staff. The patients
13 were positive about the experience of group physiotherapy [social influences], gained understanding
14 of their condition [knowledge], skills and confidence in its SM [beliefs about capabilities], but would
15 have liked it to be longer than six weeks [environmental context and resources] for further support.

16

17 **Literature reviews**

18 The consolidated definition of an intervention that promotes SM was designed to address both the
19 process and outcomes related to SM that the SOLAS intervention could address [See Additional file
20 4]. The rapid review found comparable effectiveness of physiotherapist-led group education and
21 exercise interventions and individual physiotherapy or medical management for pain and disability
22 outcomes in OA or CLBP [12]. Nonetheless, the high priority raised by physiotherapy managers to
23 implement an evidence-based group SM programme rather than continuing with individual
24 treatment, and the putative beneficial effects of group-based SM programmes [19] confirmed our
25 decision to develop a group SM programme that would meet the needs of the local population.

26 From the rapid review the FASA intervention [35] was selected as the prototype for adaptation that

1 fulfilled our consolidated SM definition, being an education and exercise intervention based on the
2 evidence-based ESCAPE programme for OA knee [45], designed for people aged over 50 years with
3 OA hip, knee and/or lumbar spine, which has been found to be clinically effective compared to
4 standard GP care (personal communications, N Walsh). FASA was designed to be delivered by one
5 physiotherapist in groups of up to eight people and considered acceptable and feasible to support
6 SM by healthcare professionals in the UK [46]. In the FASA trial it was delivered by trained research
7 physiotherapists in UK healthcare settings and had not been previously delivered by health service
8 physiotherapists in any jurisdiction including Ireland. We contacted the FASA intervention developer
9 [N Walsh] who agreed to collaborate, provided and discussed the intervention materials, and
10 allowed our team to observe its delivery in several UK settings. From this we believed it had the
11 potential to meet our target population and health service needs but would need formal evaluation
12 to establish if it was fit for purpose, acceptable to Irish primary care physiotherapists and required
13 adaptation prior to evaluation in the planned feasibility trial.

14
15 Within the most recent clinical guideline recommendations for OA and CLBP the most consistent SM
16 behaviours for programmes to promote/change within participants were a continuation or increase
17 in physical activity, the use of joint specific exercise and pharmacological and non-pharmacological
18 pain management approaches, with varying recommendations for healthy eating/weight
19 management and pacing for OA and the use of active coping strategies for CLBP. The strategies that
20 interventions should adopt to support SM behaviour ranged from none [5], [7] to highly specific [4],
21 [47]. An additional file provides details of these findings [See Additional file 5]. Three psychological
22 factors that mediated (i.e. determinants) pain, disability and functional outcomes of interventions
23 targeting these SM behaviours in chronic musculoskeletal pain were identified from the literature;
24 i.e. increasing self-efficacy for OA and CLBP [48],[49], and reducing pain catastrophizing [48], [50],
25 and fear [51] for CLBP. The literature reviews of behaviour change theories and techniques found
26 variable integration in included studies, with social cognitive theory being the most frequently

1 applied, and identified the most commonly used BCTs in group-based SM programmes as outlined in
2 Additional file 4.

3

4 **Focus Groups**

5 Following inter-rater reliability checks (>95% agreement) [52], the focus groups resulted in 29
6 themes related to feasibility: programme participants (n= 5), content (n= 7), structure (n= 9) and
7 delivery (n=8). The most frequent theme was the feasibility of recruiting sufficient numbers of
8 suitable participants, at the right time to participate, with varying views expressed on the optimal
9 number for a successful group [6 to 14]. Opinions were mixed about the acceptability of including
10 participants with CLBP, in addition to OA, and those below 50 years as within FASA [35], but
11 considered essential to recruiting sufficient patients to ensure the intervention's long-term viability.
12 Physiotherapists were positive about the combined SM education and patient-led group exercise
13 model of FASA, but felt 20 minutes was insufficient for education and discussion, one hour was too
14 short to run the group effectively, and two sessions per week as delivered in FASA while ideal was
15 not acceptable from service or patient perspectives. An additional file provides further details of the
16 feasibility analysis [see Additional file 6].

17

18 The findings of the barriers and enablers analysis identified 13 of the 14 TDF domains and 30 themes
19 that predominantly related to the physiotherapists [n=13] who would deliver the intervention, the
20 target participants [n=10], the intervention [n=3], general practitioners (GPs) [n=2] and local
21 organisations [n=2]. The majority of perceived barriers to delivering the intervention prototype were
22 within the TDF environmental context and resources domain, beliefs about capabilities to deliver the
23 intervention as intended and beliefs about its consequences. The key enablers were similar to the
24 findings of the manager interviews. The significant influence of referring GPs as potential barriers

1 and enablers to changing client attitudes, beliefs and expectations of the role of physiotherapy in
2 promoting SM were also highlighted. From the participant perspective the main barriers perceived
3 by physiotherapists to be addressed were patients' limited knowledge and skills in engaging in SM
4 behaviours, particularly physical activity and exercise, low motivation to self-manage and regulate
5 their behaviour, and negative emotions about participating in a group. Further details of these
6 findings are provided in an additional file [see Additional file 4].

7

8 The resource capacity checklist findings showed that most physiotherapy sites (95%; n=19) met the
9 criteria to be considered eligible ($\geq 60\%$) to deliver the intervention prototype within existing
10 capabilities or with essential modifications to facilities, equipment or staffing. Further details of
11 these findings are provided in additional files [see Additional files 3 and 4].

12

13 Following this detailed needs assessment, the overall programme goal of SOLAS was defined as
14 promoting SM behaviour for people with OA hip/knee and/or CLBP in everyday life. The findings of
15 the needs assessment informed several key decisions in designing the intervention. One, a number
16 of determinants of the outcome of SM interventions in people with OA and CLBP identified from the
17 literature (self-efficacy, motivation, catastrophizing, fear), focus groups (knowledge, skills,
18 motivation, fear, behaviour-regulation) and expert consultation (behaviour regulation) were to be
19 targeted within SOLAS (two of which were absent from FASA, i.e. catastrophizing, motivation; see
20 Table 2). Two, a specific behaviour change theory, self-determination theory (SDT), was selected to
21 underpin participants' uptake and engagement in the SOLAS intervention target behaviours as non-
22 adherence to physical activity, exercise and diet is well recognised in the literature in these
23 populations [53],[54]. SDT emphasises the importance of autonomy and autonomous self-regulation,
24 core components of self-management behaviour [55]-[57]. According to SDT, social agents such as

1 healthcare practitioners can influence an individual's autonomous motivation for behaviour through
2 their interpersonal style and interaction with the individual. A supportive interpersonal style satisfies
3 an individual's psychological need for autonomy, competence and relatedness leading to increased
4 levels of autonomous motivation for the behaviour. Previously, SDT has been successfully applied to
5 group-based education, exercise [58]-[61], physical activity [62], weight management [63],
6 medication adherence [64], diabetes SM [65], and individual physiotherapy interventions [40], [66]-
7 [68]. Several needs supportive interpersonal strategies were identified from the literature to support
8 physiotherapists' effective delivery of the intervention using an SDT approach [58], [66],[67],[69]
9 that would be operationalised during the physiotherapist training programme [Step 5]; e.g.
10 providing meaningful rationale for SM behaviours, acknowledging participants' feelings and
11 perspectives, and offering opportunities for participant input. Three, although the intervention
12 prototype was found to be broadly consistent with current guidelines for OA, the SOLAS intervention
13 would address the need for more evidence-based information on healthy weight, nutraceuticals and
14 acupuncture [6]. Four, as FASA was not designed for non-specific CLBP, additional education content
15 on the nature of CLBP, active coping strategies, and current recommendations for acupuncture and
16 TENS were needed. Finally, the education content required adaptation to reflect socio-demographic
17 statistics related to physical activity, obesity, OA and LBP within the Irish population [3]. An
18 additional file details the process of adapting the SOLAS intervention [see Additional file 5].

19

20 *Insert Table 2 and Figure 2 approximately here*

21

22 **Step two: identification of outcomes, performance objectives and change objectives**

23 The specific intervention SM behavioural outcomes are:

24 i. To increase the physical activity level of participants

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Insert Table 4 approximately here

Step four: creating an organised programme plan

The consensus building workshop held nine ballots for proposed adaptations to the FASA prototype structure, physiotherapist training and participant recruitment procedures of which eight were carried (Table 5). It was agreed that the definitive SOLAS intervention would comprise six weekly sessions of 90 minutes [45 minutes education/discussion and 45 minutes exercise] for people aged at least 45 years to be delivered by one physiotherapist in groups of 4-8 participants with OA of the hip, knee, lumbar spine and CLBP. The adapted education content was incorporated into the new structure (Table 6), and new programme materials were adapted from FASA (i.e. intervention slides and script, participant programme handbook, exercise photographs of an age appropriate model). A review of FASA for evidence-based materials to enhance physical activity, healthy eating, weight management and pain coping strategies (see Additional file 5) identified the need for additions to SOLAS as indicated in Table 6.

Insert Tables 5 and 6 approximately here

Step five: adoption and implementation plan

The programme use outcomes are:

- i. PCCC Physiotherapy managers adopt the SOLAS intervention and participant recruitment procedures
- ii. PCCC Physiotherapists implement the SOLAS intervention and participant recruitment procedures

1 The specific performance objectives for each programme use outcome are presented in Table 7. The
2 determinants of physiotherapist behaviour identified from the needs assessment were mapped to
3 the performance objectives to articulate the specific change objectives. An additional file shows the
4 matrix of change objectives in detail [see Additional file 8]. A range of theoretically derived BCTs and
5 practical strategies were selected by the intervention development group to target the change
6 objectives of adoption and implementation as detailed in Table 8. For example, in order to influence
7 the determinants physiotherapists' knowledge, skills, beliefs about capabilities and beliefs about
8 consequences to deliver the SOLAS intervention linked to the performance objective
9 physiotherapists "complete training in the delivery of the SOLAS intervention" a bespoke training
10 programme underpinned by selected BCTs was developed.

11

12 *Insert Tables 7 and 8 approximately here*

13

14 **Step six: creating an evaluation plan**

15 A cluster randomized controlled feasibility trial has been designed to evaluate SOLAS [Current
16 Controlled Trials ISRCTN49875385, 26th March 2014] [36]. A cluster randomised trial design was
17 chosen to avoid contamination of the control group [25]. The most appropriate comparison was
18 considered usual treatment [20], defined as individual physiotherapy care. The trial aims to assess
19 the acceptability and demand of the SOLAS intervention to patients and physiotherapists compared
20 to usual treatment [70], the feasibility of trial procedures and the most efficient and effective study
21 design for a definitive trial. In the absence of a suitable validated SM outcome measure from the
22 literature [12],[71],[72], a new measure was developed for evaluation within the feasibility trial. A
23 range of effect and mediation outcome measures were selected from the literature to be evaluated
24 within the trial. A detailed fidelity protocol has been developed and published separately [73]. The

1 pilot trial resulted in further minor adaptations to the intervention content and materials, enhanced
2 physiotherapist training from 1.5 to two days (more emphasis on goal setting, problem solving, and
3 feedback) and amended participant eligibility criteria (CLBP participants age ≤ 30 years) prior to
4 commencement of the main feasibility trial in September 2014.

5

6

7 **Discussion**

8 This study provides a detailed example of the systematic application of the IM protocol to develop
9 the SOLAS theory driven evidence-based group intervention to promote self-management in people
10 with OA hip/knee and/or CLBP through adaptation of an existing evidence-based programme. There
11 is currently limited literature on the detailed reporting of the critical development phase of complex
12 interventions in primary healthcare and the application of IM in chronic musculoskeletal pain or
13 physiotherapy and this study should inform future researchers in this evolving field. We followed all
14 the recommended steps within IM [32], engaged a representative sample of stakeholders using a
15 mix of qualitative and quantitative methods, applied emerging behaviour change methodologies to
16 inform SOLAS intervention development and implementation, and adhered to TiDieR guidance in its
17 description [26],[74]. We believe the decision to adapt an existing intervention enhanced its uptake
18 by stakeholders, the quality of the intervention and materials, and allowed the intervention
19 development group to address the practicalities of implementation, including physiotherapist
20 training from the outset.

21

22 The SOLAS intervention provides for the first time a group intervention for people with two of the
23 most common chronic musculoskeletal conditions (i.e. OA and CLBP) presenting to primary care.

1 While the multi-joint aspect of the FASA prototype for people with OA aged over 50 years was
2 acceptable to UK physiotherapists [46], and credible to Ireland's stakeholder primary care
3 physiotherapists, it was considered necessary to adapt the diagnostic pool for SOLAS to include
4 people with non-specific CLBP aged at least 30 years to increase its acceptability to meet their
5 service needs. Further adaptations were required to implement recent clinical guideline
6 recommendations for OA and CLBP, and Irish sociodemographic statistics. Finally, the overall
7 structure of the programme was adapted from 12 twice weekly, one hour sessions to six once
8 weekly, 90 minute sessions despite some patients and physiotherapists expressing support for a
9 longer programme. Nonetheless, the majority of physiotherapists believed 6 weeks reflected current
10 practice and was more realistic for patients, which is supported by a recent systematic review [75].
11 However, it has been proposed that longer programmes may provide larger treatment effects than
12 current programmes [13],[14],[75], which could be considered worthwhile by patients [76]. Similarly,
13 the decision to deliver the intervention once rather than the more frequent twice weekly reported in
14 the literature [75] was taken to enhance acceptability to local physiotherapist stakeholders as
15 demonstrated in a quote from one focus group participant '*twice a week is...a nice idea. What you*
16 *use in trials and then never use in practice*'. The feasibility trial results will inform whether these
17 decisions were correct and reflect the reality of collaborating with healthcare professional
18 stakeholders in developing interventions while also taking account of the evidence. If positive, this
19 pragmatic example of involving clinicians has the potential to enhance future knowledge translation
20 of evidence-based interventions, which is highly variable [18], and potentially hampered by
21 previously prioritising the role of clinicians as intervention deliverers to the detriment of harnessing
22 their invaluable contribution in the design phase. Using the IM process to also understand and
23 address the barriers to recruiting and retaining sufficient participants, the identification of sufficient
24 numbers of suitable clinical sites, required adaptations to facilities, equipment and staffing and
25 training requirements to support consistent intervention delivery across a range of primary care
26 health settings, enhanced our readiness to evaluate the intervention in the feasibility trial.

1 As demonstrated in this paper the IM process details how accessing and using theory can be
2 undertaken to support intervention development and implementation as highlighted in the MRC
3 framework [20]. The application of this approach allows for meaningful analysis of the underlying
4 mechanisms that are hypothesised to affect the desired intervention outcomes, by enabling the
5 explicit linking of intervention components to theory, which should lead to improved outcomes for
6 the targeted populations and an enhanced potential for intervention replication [28]. Our rapid
7 review found the majority of previous group-based SM interventions failed to report any
8 underpinning behaviour change theory or techniques [40], reducing understanding of mechanisms
9 of action, preventing replication and potentially contributing to their small effects [13],[75],[76].
10 This was compounded by the limited and variable quality of mediation studies for the target SM
11 behaviours in OA and CLBP [48]-[51], [77] that required our pragmatic selection of behavioural
12 determinants that could be targeted by the intervention. While self efficacy is an important
13 determinant of physical activity in the general population and older adults with some evidence in OA
14 and CLBP [48],[49], the more tenuous evidence for the effects of fear and catastrophizing [50], [51]
15 on SM outcomes warrants further investigation in appropriately designed and powered prospective
16 mediation studies [75]. Motivation was identified as a key determinant of SM behaviour and
17 enhanced within the intervention by selecting SDT rather than other theoretical perspectives due its
18 primary focus on an individual's need for autonomy, a core component of SM. Other prominent
19 psychological theories identified in our literature review [40],[75], such as social cognitive theory
20 [78](which was applied within FASA [35]), predominantly target constructs such as self efficacy,
21 conceptually similar to competence within SDT [79], rather than autonomy. It was also considered
22 unnecessary to include an additional behaviour change theory to target some of the other
23 determinants, as SDT has been found to positively influence other mediators (i.e. fear) related to
24 treatment [80], and the TDF provides a sound theoretical basis for targeting all our selected
25 mediators. Furthermore, the evidence for the determinants of increasing participants' SM
26 knowledge and skills exemplified in our consolidated definition and highlighted in the

1 physiotherapist focus groups was limited by their poor measurement in previous studies that should
2 be addressed in future research [12],[81].

3

4 The study is limited by comparatively less engagement with people with OA and CLBP in the
5 intervention development process that may have increased the acceptability and sustainability of
6 the intervention, but will be addressed in the feasibility trial [36]. While it would have been
7 preferable to specify the target behaviours in a more detailed way, most current OA and CLBP
8 guidelines lack specificity in relation to physical activity and dietary changes for weight management
9 [7],[82]. Indeed, recent evidence has reported health gains in those achieving below recommended
10 physical activity levels [83],[84], and there is general consensus that due to concerns about pain
11 exacerbation people with chronic musculoskeletal pain should be supported to do activity according
12 to their abilities [85],[86], as we have previously demonstrated in CLBP [87]. Nonetheless, the
13 intervention included public health recommendations for 150 minutes of moderate intensity
14 physical activity, as well as healthy eating and weight management guidance in addition to relevant
15 statistics in the Irish population to promote behaviour change. While recommendations for
16 resistance and flexibility exercises on 2 or 3 days each week [88] were conveyed to participants
17 during SOLAS, they could have been specified more explicitly within the target behaviours without
18 undermining autonomous motivation. In relation to the remaining SM behaviours recent trials
19 reporting positive effects have failed to quantify the use of pain coping skills, pharmacological or
20 non-pharmacological pain management strategies by participants thus limiting our ability to specify
21 targets [89]-[91]. Within the feasibility trial the proportion of participants achieving recommended
22 levels of physical activity and using the SM behaviours will be explored to allow their specification
23 for a future definitive trial. Finally, potential socio-cultural and environmental determinants of
24 physical activity, diet and medication adherence in the general population were not specifically
25 addressed within our intervention due to lack of evidence [92]-[94].

1 **Conclusions**

2 This study provides a detailed example of the application of the IM approach to the development of
3 a theory-driven, group-based complex intervention designed to promote self-management, for
4 evaluation in a feasibility trial. While IM is a time intensive collaborative process, the range of
5 methods and resultant high level of transparency is invaluable and allows replication by future
6 complex intervention and trial developers.

7

8 **Availability of supporting data**

9 The data sets supporting the results of this article are included within the article and its additional
10 files.

11

12 **List of abbreviations**

13 IM Intervention mapping

14 SM Self-management

15 OA Osteoarthritis

16 CLBP Chronic low back pain

17 SOLAS Self-management of osteoarthritis and low back pain through activity and skills

18 FASA Facilitating activity and self-management in arthritis

19 MRC Medical research council

20 PCCC Primary, community and continuing care

21 BCT Behaviour change technique

22 GP General Practitioner

23 TDF Theoretical domains framework

24 SDT Self-determination theory

25 TENS Transcutaneous electrical nerve stimulation

26

1 **Competing interests**

2 The authors declare that they have no competing interests.

3

4 **Author's contributions**

5 DAH conceived and designed the study, contributed to analysis and interpretation of all data,
6 drafted and critically revised the manuscript. LCM contributed to the design, data collection, analysis
7 and interpretation of the needs assessment and drafted an earlier version of the manuscript. DH
8 analysed the focus group and manager interview data, and helped to draft the manuscript. AMH
9 contributed to the design of the study, the identification of the determinants of SM behaviour,
10 outcomes, performance objective and change objectives, and helped to critically revise the
11 manuscript. ET contributed to the design, data collection and analysis of the patient interviews and
12 helped to critically revise the manuscript. SMcD contributed to the design of the study,
13 interpretation of data and helped to critically revise the manuscript. CL contributed to the design of
14 the behaviour change process of the intervention, and helped to critically revise the manuscript. NW
15 contributed to the adaptation of the FASA intervention, and helped to critically revise the
16 manuscript. SG contributed to the design and data collection of the focus group, physiotherapist and
17 patient interview studies, interpretation of the resultant data and helped to critically revise the
18 manuscript. JM contributed to the design of the study, interpretation of all data and helped to draft
19 and critically revise the manuscript. All authors read and approved the final manuscript.

20

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26

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Figure 1 Intervention mapping process, Bartholomew et al. [32]

Figure 2 Theoretical framework of behaviour change for SOLAS intervention