

1 Developing an Intervention for Fall-Related Injuries in Dementia

2 (DIFRID): an integrated, mixed-methods approach

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1 Abstract

2 Background

3 Falls in people with dementia can result in a number of physical and psychosocial consequences.
4 However, there is limited evidence to inform how best to deliver services to people with dementia
5 following a fall. The aim of the DIFRID study was to determine the feasibility of developing and
6 implementing a new intervention to improve outcomes for people with dementia with fall-related
7 injuries; this encompasses both short-term recovery and reducing the likelihood of future falls. This
8 paper details the development of the DIFRID intervention.

9 Methods

10 The intervention was designed using an integrated, mixed-methods approach. This involved a realist
11 synthesis of the literature and qualitative data gathered through interviews and focus groups with
12 health and social care professionals (n=81). An effectiveness review and further interviews and
13 observation were also conducted and are reported elsewhere. A modified Delphi panel approach
14 with 24 experts was then used to establish a consensus on how the findings should translate into a
15 new intervention. After feedback from key stakeholders (n=15) on the proposed model, the
16 intervention was manualised and training developed.

17 Results

18 We identified key components of a new intervention covering three broad areas:

- 19 • Ensuring that the circumstances of rehabilitation are optimised for people with dementia
- 20 • Compensating for the reduced ability of people with dementia to self-manage
- 21 • Equipping the workforce with the necessary skills and information to care for this patient
22 group

23 Consensus was achieved on 54 of 69 statements over two rounds of the Delphi surveys. The
24 statements were used to model the intervention and finalise the accompanying manual and protocol
25 for a feasibility study. Stakeholder feedback was generally positive and the majority of suggested
26 intervention components were approved. The proposed outcome was a 12-week complex
27 multidisciplinary intervention primarily based at the patient's home.

28 Conclusions

29 A new intervention has been developed to improve outcomes for people with dementia following a
30 fall requiring healthcare attention. The feasibility of this intervention is currently being tested.

31 Trial registration

32 ISRCTN41760734 (16/11/2015)

- 1 Keywords

- 2 dementia; falls; intervention development; Delphi consensus; realist synthesis

1 Background

2 People with dementia who live in their own home make up 70% of all people living with dementia in
3 the UK [1], and are ten times more like to fall as people without dementia [2]. The negative
4 consequences of falls are greater for people with dementia than for other older people [3]. While
5 even non-injurious falls can result in psychosocial consequences such as loss of confidence and fear
6 of falling [4], functional decline in people who sustain injuries may be greater than in those who do
7 not sustain injuries [5, 6]. Despite this, few trials have specifically addressed the management of fall-
8 related injuries in people with dementia. While multifactorial interventions by specialist falls services
9 are effective in preventing further falls in older people without dementia [7, 8], evidence of their
10 effectiveness for people with dementia is inconclusive [9-11]. Similarly, falls-prevention exercise
11 programmes such as Otago [12] have little evidence of efficacy for people with dementia, though
12 some work has been done on tailoring the programme for individuals [13, 14]. There is, however,
13 some evidence that rehabilitation interventions may result in improvements in motor performance
14 in people with dementia [15] and that motor training can increase physical activity in people with
15 dementia without increasing the risk of falls [16]. Recently published guidelines acknowledge that
16 multifactorial falls interventions may not be suitable for a person living with severe dementia, but
17 provide no recommendations on how to optimise falls interventions for this patient group [17].

18 The brief for this study was therefore to develop a new complex intervention to improve care for
19 community-dwelling people with dementia with fall-related injuries. In response to calls for a more
20 systematic approach to, and greater transparency in, intervention development [18-20], this paper
21 describes the development process in detail. This includes presenting (a) the causal factors and
22 change mechanisms underpinning falls and rehabilitation care for this patient group; (b) the
23 outcomes of a consensus-seeking process based on this initial work; (c) the development of a logic
24 model; and (d) the development of intervention materials.

1 Methods

2 The development of the intervention involved qualitative work to map existing care pathways [21]
3 and explore the views of stakeholders on the content and delivery of a new intervention [22]; an
4 effectiveness review [5]; a realist synthesis of the literature; a prospective diary study to provide
5 information on recruitment sources and existing service use; consensus panel meetings of experts; a
6 Delphi survey; and further qualitative work to elicit stakeholder feedback on the proposed
7 intervention. The findings were then used to develop a logic model, protocol [23] and intervention
8 materials. The feasibility and acceptability of the new intervention is currently being evaluated.
9 Figure 1 illustrates the process of intervention development.

10 [Figure 1 here]

11 *Figure 1: Intervention development*

12 Identifying causal factors and change mechanisms

13 Qualitative work and formative realist analysis

14 The initial qualitative work comprised 58 semi-structured interviews and 5 focus groups with health
15 and social care professionals (full details of qualitative work are reported elsewhere [22]; this also
16 included observation of care delivery and interviews with patients and carers, although these were
17 not included in this formative work due to the timescales involved). Professionals were identified
18 through snowball sampling facilitated by local study investigators. Recruitment continued until data
19 saturation was reached. Details of participants are provided in additional file 1. Interviews and focus
20 groups were audio recorded, transcribed, and anonymised prior to analysis.

21 We used realist methodology [24, 25] to identify both causal factors and change mechanisms. This is
22 an approach to literature review and data analysis which seeks to answer the question 'what works
23 for whom under what circumstances, how and why', describing mechanisms which produce
24 particular outcomes in specific contexts [26]. Members of the qualitative team (AW, CB) generated
25 first "if-then" statements and grouping these according to emerging themes [27]. We refined the if-

1 then statements, looking for data that could be interpreted as a causal factor or a change
2 mechanism. We expressed these using the realist framework of Context, Mechanism or Outcome
3 [25], with mechanisms further divided into – ‘resource’ (the intervention component added) and
4 ‘reasoning’ (what change this resource will produce) [28]. Finally, we presented these initial Context-
5 Mechanism-Outcome configurations (CMOCs) to a panel of clinicians (LA, RB, CF, SP, LR) and further
6 refined them based on their feedback. This framework formed the basis for extracting data from the
7 literature. For examples of finalised CMOCs, see table 1.

8 *Effectiveness review*

9 This has been reported elsewhere [5]. The review could not draw definitive conclusions, since few
10 interventions were aimed at patients with dementia, and those that were focused mainly on hip
11 fracture. It therefore indicated that the development of a new intervention was warranted.

12 *Realist synthesis*

13 The protocol for the realist synthesis was registered with PROSPERO (CRD42016040059).

14 *Search strategy*

15 Searches were limited to English. Initially we undertook a comprehensive search (SR). This took place
16 in November 2015, and was designed to provide a clear understanding of the interaction between
17 interventions, characteristics of people with dementia and contextual factors around a fall. Iterative
18 targeted searches aimed to build on that understanding and were completed by March 2017 (FB). As
19 the aim of the paper is to describe the intervention development process as it occurred, the
20 searches have not been updated.

21 Comprehensive searches were conducted in MEDLINE, CENTRAL, Health Management Information
22 Consortium, EMBASE, CINAHL, Web of Science, Allied and Complementary Medicine Database, and
23 Physiotherapy Evidence Database (PEDro) (see additional file 2 for an example search strategy).
24 Trials registers were searched, but further grey literature searching was not conducted. Results from
25 all databases were imported to Endnote. Targeted searches took place in MEDLINE and CINAHL on

1 EBSCO (see additional file 3 for an example targeted search strategy). Additional papers were
2 identified through citation chaining of included papers and relevant systematic reviews and hand
3 searches. Figure 2 demonstrates the flow of studies.

4 [Figure 2 here]

5 *Figure 2: Diagram of the search, screening, selection and extraction process*

6 *Data extraction and CMOc refinement*

7 Data were extracted from included papers using a bespoke online form. This included methodology,
8 appraisal using the Mixed Methods Appraisal Tool [29]; an intervention description, as applicable,
9 using the TIDieR framework [30]; and evidence describing contexts, mechanisms or outcomes. Data
10 were extracted by two reviewers independently, one clinician (LA, BB, CF, SP, SL) and one non-
11 clinician (CB, FB, CS, AW). Data were discussed at a meeting of reviewers and disagreements
12 resolved. The qualitative team (CB, CS, AW) analysed and summarised the data. Following this
13 process, the wording of each CMOc and the set of themes were refined (CB, CS, AW). The process
14 was repeated for the additional papers identified through targeted searches and citation chaining.

15 *Delphi consensus process*

16 We convened a multidisciplinary panel of 24 expert health and social care professionals (see additional
17 file 1) to review the initial findings and make recommendations regarding the design of the complex
18 intervention using a modified Delphi panel approach [31-33] (see additional file 4). Panellists were
19 selected who (1) represented of a range of stakeholder groups identified to be important to the care
20 of people with dementia who fall; (2) were in contact with people with dementia who fall and/or (3)
21 had relevant academic expertise; (4) and were able to attend face-to-face meetings. The consensus
22 panel meetings were audio recorded (with the consent of participants) and transcribed for analysis.

23 *Consensus panel meeting 1*

24 Prior to the first meeting (March 2017), the panel received summaries of the qualitative work,
25 effectiveness review, and the realist synthesis. At the meeting, members were split into groups to

1 discuss three key aspects of the intervention: feasibility and setting; content; and outcome measures.
2 Each group discussed all issues. Key points from the discussions were fed back and areas of initial
3 agreement and dissent were identified.

4 Delphi surveys

5 Following the first consensus panel meeting, a series of statements were identified and sent to panel
6 members via an online survey tool. Members were asked to respond to specific questions regarding
7 feasibility of the setting; staffing and training requirements; components of the intervention; and
8 outcome measures for the feasibility study. A threshold of two-thirds agreement of those completing
9 the survey was chosen to represent consensus. Responses were received from 14 panel members.
10 Since consensus was not achieved on all items, a second round of the survey was conducted which
11 included the results of the first round. This gave members the opportunity to revise their responses.
12 Responses were received from 13 panel members.

13 All respondents completed all items in both rounds of the survey. To facilitate free expression of
14 opinion, only the independent moderator (BE) could access non-anonymised data. Statements
15 included in the survey along with consensus results are given in additional file 5.

16 Stakeholder feedback

17 In parallel with the surveys, additional focus groups and interviews were conducted with a range of
18 stakeholders to explore the feasibility and acceptability of the draft intervention (see additional file 1
19 for details of participants). These were invited from the pool of participants who took part in WP2,
20 supplemented by snowball sampling of professionals and additional patients and carers recruited via
21 the North East and North Cumbria CRN Case Register. Interviews and focus groups were audio-
22 recorded, transcribed, and anonymised prior to thematic analysis.

1 Consensus meeting 2

2 At the second meeting (June 2017), panel members considered the draft protocol for the feasibility
3 study; results of stakeholder feedback on the proposed intervention; and the proposed roles of
4 members of the multidisciplinary team (MDT). Small group discussions were facilitated as at the first
5 meeting.

6 Collation of results and development of a logic model

7 We collated the findings of the final round of the Delphi survey, consensus panel discussion, and
8 stakeholder feedback to finalise the protocol for the feasibility study and model the intervention.

9 The logic model was developed by the qualitative team (CB, AW) informed by existing logic model
10 templates [34, 35] and was discussed by the Trial Oversight Committee (TOC).

11 Preparation of intervention resources

12 Three specific resources needed to implement the intervention were identified from the protocol
13 and logic modelling process: an assessment document, a manual and a staff training programme.

14 These were developed by the study team (LA, CB, EF, AS, AW) with reference to the final consensus
15 statements, protocol, and logic model and were further discussed by the TOC and all co-
16 investigators.

17 Results

18 Nine CMOcs were identified as key components of a new intervention for people with dementia
19 following a fall. These were grouped into three themes:

- 20 • Ensuring that the circumstances of rehabilitation are optimised for people with dementia
21 (CMOcs 1-3)
- 22 • Compensating for the reduced ability of people with dementia to self-manage (CMOcs 4-6)
- 23 • Equipping the workforce with the necessary skills and information to care for this patient group
24 (CMOcs 7-9)

1 In presenting each CMOc, we synthesise evidence from the literature, map relevant consensus
2 statements, describe how intervention components agreed by the consensus process were
3 operationalised for the DIFRID intervention, and present results of stakeholder feedback. A fourth
4 theme, covering practicalities relating to intervention delivery and evaluation, is also discussed.
5 Quotations presented are identified by a unique participant ID. Additionally, role and service type is
6 provided for professionals. All identifying information, including location, has been removed to
7 maintain confidentiality.

8 Theme 1: Ensuring that the circumstances of rehabilitation are optimised for people 9 with dementia

10 This theme concerns the ways in which broader contextual factors, such as setting and
11 comorbidities, can affect the engagement of people with dementia in interventions. The outcomes
12 of the consensus survey and operationalisation of each CMOc are shown in Table 1.

13 [Table 1 here]

14 CMOc1: Managing pain

15 Pain is associated with impaired mobility and physical functioning [36-38] and increased agitation
16 and aggression [39-42] in people with cognitive impairment or dementia. Sleeping and mood
17 disorders in people with dementia have also been linked to higher pain levels [43]. People with
18 dementia who are in pain may therefore find it more difficult to engage fully with an intervention.
19 However, recognising pain in people with dementia can be challenging as they may be unable to
20 verbally communicate their pain [44].

21 The consensus panel agreed that identifying pain should be part of the DIFRID intervention.
22 Stakeholders highlighted the complexities of assessing pain in people with dementia:

23 *There are so many different implications. It is not just about us scoring pain. If you*
24 *are talking about pain assessment, you need to do it properly. That, again, is*

1 *multi-factorial. You need to use the appropriate pain scoring. If you are talking*
 2 *about people who have got moderate dementia who are cognitively impaired,*
 3 *you need to be thinking about something like the Abbey Pain Scale or something*
 4 *like that. It is not verbal. It is behavioural, body language, facial expressions, all*
 5 *that sort of stuff.*

6 ***(Prof 122, pain nurse, focus group with specialist nurses)***

7 **CMOc2: Ensuring a supportive environment**

8 People with dementia may become distressed in an unfamiliar environment, resulting in an
 9 exacerbation of symptoms [45]. Moreover, since people with dementia may find it difficult to
 10 articulate basic needs, such as hydration, these may go unrecognised by staff [45]. Carers in one
 11 qualitative study described negative experiences of hospitalisation, such as a deterioration in
 12 patients' health, and were keen to avoid readmission [46]. Home-based exercise interventions have
 13 been shown to be feasible for at least some patients with cognitive impairment and hip fracture [47-
 14 50], though some studies reported problems with adherence [51]. Literature relating to patients
 15 with other fall-related injuries was not found.

16 The consensus panel agreed that the home environment would be the most appropriate location for
 17 the DIFRID intervention. Stakeholder feedback on this aspect of the intervention was generally
 18 positive, although some stakeholders highlighted the need for flexibility:

19 *I don't know how that would fit in, because we used to enjoy walking, you see, up*
 20 *in the hills, and I'm not quite sure how that would fit in with physio in the home.*

21 ***(Interview, Patient 15 and Carer 15)***

22 The intervention, therefore, can be delivered in the most appropriate environment for the activities
 23 and goals identified by participants.

24 **CMOc3: Adopting a holistic approach**

25 Holistic assessments to discover and manage falls risk factors emerged as an important theme.

26 Comorbidities that increase mortality risk during and after hospitalisation for hip fracture in older

1 people may go unrecognised and undiagnosed [45, 52, 53]. Psychosocial factors, such as depression
 2 [53, 54] and social isolation [54], may also be important for the wellbeing and recovery of people
 3 with dementia following a fall. Holistic assessments, such as Comprehensive Geriatric Assessment
 4 (CGA), have been shown to improve outcomes for people with cognitive impairment or delirium who
 5 have fallen [53-55]. Holistic assessment may also aid patient and caregiver understanding of the
 6 causes of falls [56] and facilitate early intervention for other health issues which might otherwise
 7 undermine therapy [57].

8 Stakeholders suggested including a social worker in the DIFRID MDT to facilitate assessment of social
 9 circumstances:

10 *I think it's really important that people get a review of their social circumstances,*
 11 *especially if they've had a fall. Sometimes [...] the reason that they've fallen is*
 12 *that they're trying to do something that they would benefit from having a care*
 13 *package to prevent them having to do themselves.*

14 ***(Prof 71, reablement support worker, focus group at specialist inpatient***
 15 ***rehabilitation unit)***

16 The consensus panel subsequently agreed that a social worker should be available on referral.
 17 Additional areas for assessment suggested by stakeholders included: foot assessment; nutrition;
 18 frailty; existing equipment and aids; and a detailed cognitive profile. Details of the assessment,
 19 conducted using skilled observation or verbal report from patient and carer, are shown in table 2.

20 **Table 2: Sections of the assessment and intervention document**

Generic assessment (by physiotherapist or occupational therapist)	
Falls history	
Falls risk assessment (including fear of falling, nutrition, fluid intake, pain, urinary incontinence, bowel incontinence, supportive footwear, visual impairment not corrected with glasses)	
Past medical history and comorbidities	
Medication	
Current activity levels	
Challenging behaviour and sleep disturbance	
Assessment of the needs of the informal carer	
Current mobility	
Physiotherapy assessment	Occupational therapy assessment

Posture and general observations of pain, sensation and tone	Details of home environment
Lying and standing BP	Self-care and productivity
Range of movement	Cognition
Muscle power	Task observations
TUG	Functional difficulties relating to spatial awareness, vision and hearing
Intervention planning	
Needs list	
Action planning and patient goals	
MDT record	
Referrals	

1

2 Stakeholders emphasised the need to interpret the results of holistic assessment and identify clear
3 processes for addressing issues raised:

4 *For example, incontinence, you know, you are not going to engage someone in an*
5 *exercise programme, or encourage them to stabilise their gait, their balance or*
6 *posture if actually their real problem is they are retaining urine. They are getting*
7 *overflow, and when they stand up to go they have a real sense of urgency and*
8 *they are desperate. You can put in every intervention you like. Unless you address*
9 *that problem... You need someone who is going to think about that, and*
10 *understand what is going on. The reason they are in a hurry to get up and go to*
11 *the loo is not because they are going frequently. They frequency is due to another*
12 *problem that hasn't been picked up.*

13 ***(Prof 122, pain nurse, focus group with specialist nurses)***

14 In developing the assessment and intervention materials, we therefore added a section dedicated to
15 referrals for issues identified during assessment, and tasked the MDT with reviewing this. A
16 substantial component of the DIFRID staff training programme focused on using the assessment
17 document and managing any problems identified.

1 Theme 2: Compensating for the reduced ability of people with dementia to self-
2 manage

3 This theme concerns the ways in which intervention delivery can be adapted to compensate for the
4 symptoms and challenges of dementia. The outcomes of the consensus survey and
5 operationalisation of each CMOc are shown in table 3.

6 [Table 3 here]

7 **CMOc4: Embedding interventions in day to day life**

8 Individually tailoring exercises to the preferences, interests, and physical and cognitive abilities of
9 people with dementia has been described as 'vital' to successful interventions for this patient group
10 [49]. Cognitive impairment may affect the ability of patients to follow instructions and consequently,
11 rehabilitation success [47, 51, 53-55, 58-62]. However, some people with dementia may have
12 relatively well preserved procedural memory which may enable them to form new habits [54].
13 'Embedding' interventions into existing routines could also help make them habitual [63-65].
14 Effective tailoring requires specialised training for staff and carers involved in intervention delivery
15 [49, 66]; including a staff training component in the intervention was therefore seen as essential (see
16 CMOc8).

17 Stakeholders agreed with the consensus panel's recommendation to use the principles underlying
18 the Otago exercise programme (i.e. individually tailored; progressive; stable and sustainable; and
19 using walking alongside strength and balance) [12], although they indicated that implementation of
20 this programme is often inconsistent with the recommended format due to resource limitations.
21 Stakeholders emphasised that meaningful activities should include mental and social stimulation as
22 well as physical activity:

23 *This gentleman had really bad dementia. He had sundown so he was up all night.*
24 *The family came in, and we had a game of dominos. I couldn't communicate with*
25 *him. You bring out the dominos and he won every time. It was like a different*

1 *person came out in that dominos. [...] Then, by making him stay awake all day*
 2 *and doing meaningful activities to keep him active, he was more likely to sleep at*
 3 *night. [...] He is not getting up and falling over.*

4 ***(Prof 121, focus group with specialist nurses)***

5 Music and dance were also considered particularly valuable. Exploring the barriers (including cultural
 6 barriers) to meaningful activity was identified as one way to increase the likelihood of successfully
 7 engaging patients in new activities.

8 While setting patient-centred goals achieved a high level of consensus among the panel, some
 9 stakeholders had reservations about how this might work in practice:

10 *I don't think I could do it. Like, make a cup of tea. I wouldn't trust myself.*

11 ***(Interview, Patient 13)***

12 Professional stakeholders also identified potential problematic elements of goal setting, including
 13 the difficulty of engaging people with dementia in setting goals, the potential for them to lose
 14 interest in things they previously enjoyed, and ensuring goals were those of the patient and not only
 15 the carer.

16 **CMOc5: Providing ongoing support**

17 One quarter (24%) of re-admissions following hip fracture surgery are due to 'failure of
 18 rehabilitation'—including deterioration, further falls, and inability to cope[57]. This suggests that the
 19 duration and/or dosage of existing rehabilitation may be insufficient. , As people with dementia
 20 typically have difficulties with problem solving and self-management, providing only short-term
 21 interventions may be particularly problematic for this patient group. Professionals in the initial
 22 qualitative study felt that existing interventions were often too short and lacked continuity in
 23 content and staffing [21]. They proposed regular follow-up and review to help identify new problems
 24 or relapses and maintain continuity of care.

1 The intensity and duration of the intervention proved to be the most contentious aspects of the
2 intervention among the consensus panel and stakeholders. Ultimately, the consensus panel were
3 constrained by the realities of the project timescale, which could only accommodate a twelve-week
4 intervention period. Providing on-going support was therefore not feasible. However, the panel
5 allowed for up to a total of 22 intervention sessions over twelve weeks; this is substantially more
6 than is provided by many existing services, which our initial qualitative work found were typically
7 provided for between two and six weeks. The Delphi survey therefore included questions on setting
8 appropriate boundaries.

9 All groups of stakeholders stressed the need to tailor the number of intervention sessions to the
10 individual. However, community-based professionals, particularly those in rural areas, raised
11 concerns over the feasibility of delivering this number of sessions both within and outside the
12 context of a trial. The duration of individual sessions and the intervention overall were also queried
13 by some participants:

14 *You need at least, you know, half of that time even strike up a rapport, for them*
15 *to remember, possibly, who you are, for you to engage with the carer, and that's*
16 *before you've even done anything and before you've even assessed the person or*
17 *given them any intervention. That's every time, because every time is like a new*
18 *time.*

19 ***(Prof 124, physiotherapist, focus group with community health and social care***
20 ***professionals)***

21 Other participants questioned whether the allotted twelve weeks would be long enough for all
22 referrals to have been acted upon and for alternative services to have been put in place to provide
23 ongoing support. Carers also expressed concern about what would happen after the intervention:

24 *That would be my only concern. You're leaving people, then, in limbo. You're*
25 *offering them something that isn't there anymore. It was there, but 'oh, that's not*
26 *there now'.*

1 ***(Interview, Carer 12)***

2 The intervention therefore includes mid-point and final review sessions, where intervention staff
3 check the status of referrals, treat new issues arising during the intervention period, and signpost
4 participants to other relevant services (such as activity groups) to help maintain progress after the
5 completion of the twelve-week intervention.

6 **CMOc6: Involving carers in intervention delivery**

7 The involvement of family carers is frequently recommended to improve adherence and outcomes
8 of interventions [53, 54, 67, 68]. However, this implicitly assumes that carers have capacity and the
9 skills to assist in intervention delivery. Many family carers report feeling isolated, helpless, and
10 overstretched by providing care as well as dealing with their own health problems and other
11 commitments [46, 67]. Having realistic expectations of carers is therefore important [69]. Factors
12 shown to facilitate carer involvement include exploring concerns about time requirements and
13 disruption to routines [70], understanding that carers may have difficulty of acknowledging that they
14 need help [70], and explicitly discussing potential benefits of a rehabilitation intervention to both
15 people with dementia and carers [70-73]. Carers may also benefit from interventions tailored to
16 their own needs [66, 74-77]. Carer behaviours, such as preventing the person with dementia from
17 moving around in order to avoid falls, can negatively influence the relationship between carer and
18 patient [46] and impede recovery.

19 The consensus panel agreed that educating patients and carers about positive risk and falls
20 prevention was important. This was also deemed beneficial by stakeholders:

21 *The physios and OTs [...] can assess whether or not that person needs signposting*
22 *to have some more help. I'm not saying you'd have to have somebody come in*
23 *with them and do the carer support, but I do think that training them what to*
24 *look out for, carer fatigue and the stress side of things.*

25 ***(Interview, Carer 12)***

1 However, professionals also emphasised the importance of ensuring that carer needs do not
2 overshadow those of the patient. To address this concern, the DIFRID training programme includes
3 advice on managing triadic consultations.

4 Theme 3: Equipping the workforce with the necessary skills and information to care 5 for people with dementia

6 This theme concerns both the training needs of staff and the practical organisation of interventions
7 to improve information gathering and communication. The outcomes of the consensus survey and
8 operationalisation of each CMOc are shown in table 4.

9 [Table 4 here]

10 CMOc7: Developing a detailed understanding of the patient

11 A detailed understanding of the patient is fundamental providing tailored, person-centred care in
12 dementia. As people with dementia may struggle with giving full and accurate medical histories [45,
13 57, 78], direct observation of the patient in the environment in which they fell was recommended by
14 professionals in the initial qualitative study [22]. Additional context or confirmation can be provided
15 by carers [45, 46] or patients' GPs [78]. Drawing on carer expertise to facilitate the care of people
16 with dementia in hospital has been shown to be effective in reducing agitation and distress and
17 improving carer satisfaction, though levels of patient satisfaction were not reported [60].

18 Stakeholder feedback about this aspect of the intervention was positive, particularly around using
19 carers as information sources. Professionals also agreed that assessment by observation was
20 important, particularly with regard to how participants get around the house.

21 CMOc8: Equipping staff members with appropriate skills

22 Staff members may lack specific training in working with people with dementia and their families,
23 and negative views about people with dementia and their ability to participate in an intervention
24 have been reported [66, 75-77]. Several authors recognised the value of providing specialised

1 training of staff to work with older adults and people with dementia, though few provided detailed
2 information on the content of such training [78-80]. Data from the qualitative study suggests training
3 should cover dementia-specific adaptation to practice, as well as challenging negative attitudes
4 towards those with dementia [22]. Training in how best to engage with carers could also be
5 beneficial [60].

6 Stakeholders identified training as one of the most crucial components of the intervention:

7 *What's jumping out to me is the dependence on the staff training. From a list of*
8 *interventions none of those are really, hugely, a step away from what we cover.*
9 *But I know, definitely, still in our organisation staff still need to understand that*
10 *you can't deliver the same package to someone with a physical condition as to*
11 *somebody with some challenges, whatever they are.*

12 ***(Prof 35, dementia and falls co-ordinator, focus group with community health***
13 ***and social care professionals)***

14 **CMOc9: Improving pathways and referral**

15 Collaboration between professionals is an important factor in whether patients receive effective
16 treatment [52, 81, 82]. A range of social and contextual factors influences decisions to refer to
17 services, including lack of confidence in the service provided, reluctance to share responsibility for
18 patient care, or a perception that the patient would not benefit from the service [57, 80]. The initial
19 qualitative study found staff often lacked knowledge of local services for people with dementia with
20 fall-related injuries [22]; however, this evidence suggests that a simple lack of knowledge may not be
21 the only barrier to successful care. The advantages of formalised care pathways include increasing
22 efficiency of diagnosis and beginning treatment, increasing consistency of care, reducing risk of
23 errors, reducing costs, and improvements in staff knowledge and team relations [83, 84]. Developing
24 an evidence-based pathway requires collaboration and input from stakeholders including health
25 professionals, patients and family members [85]. Ultimately, the consensus panel agreed that
26 developing a new care pathway for fall-related injuries in dementia was outside of the scope of this

1 study, though the issues of communication and referral were addressed, and the proposed MDT
2 meetings were seen as a way of maximising use of existing pathways.

3 Stakeholders raised concerns over the feasibility of organising MDT meetings, particularly in rural
4 areas. While the use of technology could potentially enable virtual MDT meetings, issues were raised
5 over security and the need for encryption. Overall, professional stakeholders identified a need to
6 clarify the roles of each member of the DIFRID MDT; this was subsequently discussed at the second
7 consensus panel meeting. Stakeholders additionally suggested including dietitian/nutritionist;
8 Alzheimer's Society outreach workers; and advocacy advisers in the MDT. Potential benefits of
9 including a community psychiatric nurse (CPN) in the MDT were: (i) access to mental health records,
10 which provided information about dementia, medications and other interventions; (ii) the potential
11 for rapid referrals and specialist support; and (iii) the potential role of CPNs in reviewing
12 medications:

13 *[The CPN at our service] can pull up information on where people are at in terms*
14 *of the support and input that they have had already when they've last been*
15 *reviewed at memory services. She can review their medications as well which can*
16 *be really helpful.*

17 ***(Prof 71, reablement support worker, focus group at specialist inpatient***
18 ***rehabilitation unit)***

19 These additional staff have not been included in the MDT, but intervention materials signpost
20 therapists to refer to them as required.

21 [Theme 4: Intervention delivery and evaluation](#)

22 The remaining consensus statements concerned issues of practicality and feasibility for the pilot
23 study (for example, inclusion criteria, recruitment, and outcome measures).

1 Design and feasibility

2 In round one of the Delphi survey, 93% of the consensus panel agreed that a complex intervention
3 was needed. It was deemed feasible to recruit 10 patients from each of three sites to the feasibility
4 study. Defining the inclusion criteria for the intervention proved more contentious among the panel.
5 The original brief for this study was to design a new intervention for people with dementia following
6 a fall-related injury. In the initial interviews and focus groups professionals argued that early
7 intervention, prior to significant injury, would be more beneficial. The consensus panel also agreed
8 that the intervention should include patients with non-injurious falls. However, the TOC
9 subsequently strongly recommended amending this to a fall for which healthcare attention was
10 sought. Consensus regarding the time period within which patients had to be recruited following a
11 fall was not reached after two rounds of surveys. Following discussion at the second meeting, it was
12 agreed that patients could be recruited up to one month after the index fall.

13 Outcome measures

14 One aim of the feasibility study is to assess the suitability and acceptability of outcome measures.
15 While the number of falls was seen as the most appropriate outcome measure by the consensus
16 panel, other stakeholders expressed reservations about the sensitivity of this measure:

17 *There are maybe subtleties there, from my thinking, that if it was just based on*
18 *that what might seem like a fail is actually an improvement because the person*
19 *does feel more confident, is doing more things but is having non-injurious falls as*
20 *a side-line.*

21 ***(Prof 35, dementia and falls co-ordinator, focus group, community health and***
22 ***social care professionals)***

23 To address these concerns, a range of outcome measures are being used in the feasibility study,
24 including measures of function, quality of life and carer burden [23].

25 Logic model

26 A logic model (Figure 3) demonstrates the flow of intervention activities to meet project goals.

1 [Figure 3 here]

2 *Figure 3: Logic model*

3

4 Discussion

5 We used a mixed-methods approach to develop the DIFRID intervention. We identified causal
6 factors and change mechanisms through analysis of qualitative data collected in an earlier phase of
7 the study and a realist synthesis of the literature. This is summarised in three broad themes:

- 8 • Ensuring that the circumstances of rehabilitation are optimised for people with dementia
9 • Compensating for the reduced ability of people with dementia to self-manage
10 • Equipping the workforce with the necessary skills and information to care for this patient group.

11 An expert panel considered how best to translate these concepts into a new intervention. Consensus
12 among the panel on which components should be included was achieved through two rounds of a
13 Delphi survey. This process allowed us to integrate practical, empirical data from experts and
14 practitioners with evidence from previous studies to create a robust, theoretically-informed design
15 for a new intervention.

16 Despite the structured approach to intervention development, not all of the CMOcs that emerged
17 from the initial synthesis were equally present in the consensus surveys. CMOc5, for example, which
18 concerned ongoing support and follow-up of people with dementia, was deemed beyond the scope
19 of this study; panel members expressed concerns regarding practicality and feasibility of engaging in
20 such follow-up when working within constraints such as funding, existing multidisciplinary teams,
21 existing service provision, and the 12-week limit of the trial. Moreover, for practical reasons relating
22 to costing the intervention, it was difficult to allow the number of sessions to be open-ended. The
23 12-week intervention period is quite short in comparison with some trials of exercise in older people
24 [86]. However, there are a number of trials which have successfully used this intervention period. In
25 our development work, we found people with dementia received few interventions, often limited to

1 2 or 6 weeks, so a 12-week intervention is a substantial improvement [21]. Additionally, at the end
2 of the DIFRID intervention therapists are encouraged to refer participants on to community falls
3 groups or other appropriate ongoing services. It is possible that in future development of this
4 intervention we could consider extending the intervention beyond 12 weeks but this will not be
5 possible within the funding for our planned feasibility trial.

6 CMOc9 refers to the creation of a centralised pathway, which was similarly considered beyond the
7 scope of the study; instead, the consensus process focused on improving communication within and
8 between staff. Not all components were systematically translated and included in the Delphi survey;
9 this led to the omission of a statement relating to blanket pain relief as described in CMOc1, for
10 example. Potential pitfalls associated with this kind of iterative process of intervention development
11 therefore include ensuring follow-through of ideas at each stage and the potential disconnect
12 between theoretical ideals and what is considered practical and feasible in everyday practice.
13 Though we aimed to follow processes for intervention development [19, 20], these were not always
14 smoothly navigated from one stage to the next. A more rigorous approach to the process of
15 operationalising CMOcs to Delphi survey to final intervention could help to mitigate some of these
16 pitfalls.

17 The final intervention agreed is a home-based, tailored therapy intervention delivered by an MDT
18 that includes physiotherapists, occupational therapists, therapy assistants, and a geriatrician (see
19 additional file 6). Up to two assessment sessions and 22 intervention sessions will be available. The
20 resources developed include an intervention manual for staff; a holistic assessment document to
21 help staff to tailor the intervention; and a staff training programme [23]. This is in concordance with
22 guidelines that recommend multifactorial interventions for falls in older people [87]. Though some
23 evidence suggests that such interventions are not effective in people with dementia [9-11], it is
24 hoped that the individually tailored, embedded approach will help to mitigate some of the factors
25 affecting intervention success among this patient group [49].

1 The intervention that has been developed is novel in that it is tailored to the needs of people with
2 dementia and addresses both rehabilitation and the prevention of future falls in people with
3 dementia. While we are aware of a current study examining enhanced recovery of confused
4 patients following hip fracture [6], this focuses on a single type of injury. Other current studies are
5 focusing on falls interventions for people with dementia, but are not targeted at those who have
6 already had an injurious fall [88, 89]. The DIFRID intervention therefore targets a neglected group,
7 and could potentially clarify whether the preventive component is effective in patients who have
8 already fallen.

9 [Strengths and limitations](#)

10 A strength of this project lies in the theoretically and empirically-informed intervention development
11 process. While a response rate of 58% was achieved for the consensus surveys, not all panel
12 members attended the consensus meetings. Furthermore, the panel did not include patient or lay
13 representatives. The Delphi approach seemed less accessible for social care professionals, as
14 evidenced by difficulty recruiting panel members and engaging them in the surveys. These factors
15 may have implications for the results. However, the iterative nature of our approach to identifying
16 causal factors and change mechanisms and stakeholder feedback process means that the opinion of
17 these stakeholders has been considered in other aspects of the development process. While the
18 effectiveness review highlighted the scarcity of evidence and underpinned the need to develop a
19 new intervention, it was of limited value in the process of intervention development. In contrast, the
20 broader, pragmatic realist approach helped to consider underlying mechanisms, and inform
21 intervention content and delivery.

22 [Conclusions](#)

23 A new intervention has been developed to help people with dementia following a fall requiring
24 healthcare attention. We are currently assessing the feasibility and acceptability of the DIFRID

1 intervention from the perspectives of all stakeholders. If appropriate, the findings will be used to
2 refine the intervention, and then explore whether it merits rigorous evaluation [19].

3 Abbreviations

4	BP	Blood pressure
5	CGA	Comprehensive Geriatric Assessment
6	CMOc	Context-Mechanism-Outcome configuration
7	CPN	Community Psychiatric Nurse
8	CNPI	Checklist of Nonverbal Pain Indicators
9	GAS	Goal Attainment Scaling
10	MDT	Multidisciplinary Team
11	OT	Occupational Therapy/Therapist
12	PEDro	Physiotherapy Evidence Database
13	TOC	Trial Oversight Committee
14	TUG	Timed Up-and-Go test

15 Declarations

16 Ethics approval and consent to participate

17 Ethical review for the initial interviews and focus groups with professionals was provided by
18 Newcastle University Research Ethics Committee (ref BH138009) and any necessary permissions
19 obtained from research and development departments of participating Trusts. Further approvals for
20 stakeholder interviews were given by Newcastle and North Tyneside 1 Ethics Committee (reference
21 15/NE/0397); Newcastle and North Tyneside 2 Ethics Committee (reference 16/NE/0011); and the
22 Health Research Authority. Additional approvals were received from participating Trusts and Social
23 Services Departments as required. For non-statutory agencies, approval was sought from senior
24 managers. All participants gave written or verbal consent; verbal consent was sought for telephone
25 interviews with professionals and for consensus panel discussions.

1 Consent for publication

2 Not applicable

3 Availability of data and material

4 The datasets generated during and/or analysed during the current study are available from the
5 corresponding author (LA) on reasonable request. The data are not publicly available due to them
6 containing information that could compromise research participant confidentiality.

7 Competing interests

8 The authors declare that they have no competing interests.

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17 Authors' contributions

18 AW drafted the manuscript with contributions from CB. AW, CB, and CS collected and analysed
19 qualitative data. FB performed literature searches. LA, CB, RB, FB, CF, SP, CS and AW extracted data
20 and contributed to CMOc development. LA analysed the consensus survey data. LA, CB, EF, AS and
21 AW developed intervention resources. LA conceived the design of the study. DH, TH, LR and all
22 authors made substantial contributions to the design of the study, revised the manuscript critically
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- 42

1 Figures

2 Figure 1

3 **Legend:** Intervention development

4

5 Figure 2

6 **Legend:** Diagram of the search, screening, selection and extraction process

7

8 Figure 3

9 **Legend:** Logic model

10 Additional files

11 **Filename:** Additional file 1.docx

12 **Title of data:** Professional participants

13 **Description of data:** Table showing numbers of participants from various health and social care
14 professions in each stage of the project.

15

16 **Filename:** Additional file 2.docx

17 **Title of data:** Comprehensive search strategy

18 **Description of data:** Medline literature search strategy for the phase 1 comprehensive search.

19

20 **Filename:** Additional file 3.docx

21 **Title of data:** Targeted search strategy

22 **Description of data:** Example Medline literature search strategy for the phase 2 targeted searches.

23

24 **Filename:** Additional file 4.docx

25 **Title of data:** Delphi survey

26 **Description of data:** Expanded description of rationale and methodology for the Delphi survey.

27

28 **Filename:** Additional file 5.docx

29 **Title of data:** Consensus statements

1 **Description of data:** Full list of statements provided to the consensus panel along with their
2 outcomes.

3

4 **Filename:** Additional file 6.docx

5 **Title of data:** Final DIFRID intervention

6 **Description of data:** A description of the final intervention using the TIDieR framework.

7

1 Tables

Table 1: Optimising the circumstances of rehabilitation for people with dementia: CMOcs, consensus statements and outcomes				
	CMOc	Consensus statements	Outcome	Operationalisation
CMOc1	<p>Context: cognitive impairment may limit the ability of people with dementia to articulate pain</p> <p>Mechanism (resource): staff use non-verbal pain signifiers and/or give blanket pain relief</p> <p>Mechanism (reasoning): people with dementia are not in pain</p> <p>Outcome: capacity to engage with an intervention increases</p>	Tools which assess non-verbal signs of pain should be used	Agreed in round 1 (93%)	<ul style="list-style-type: none"> • Checklist of Nonverbal Pain Indicators (CNPI) [44, 90] included in assessment document • Pain management included in staff training
CMOc2	<p>Context: cognitive impairment may limit the ability of people with dementia to adapt to and cope with new environments</p> <p>Mechanism (resource): intervention assessment and delivery takes place in appropriate, accessible and familiar environments</p> <p>Mechanism (reasoning): people with dementia feel comfortable and less distracted</p> <p>Outcome: anxiety and challenging behaviours are reduced</p>	The intervention should primarily take place in the patient's home	Agreed in round 1 (86%)	Intervention delivered mainly in patient's home
CMOc3	<p>Context: the role of comorbidities may be underestimated in dementia</p> <p>Mechanism (resource): holistic biopsychosocial assessment is employed</p>	<p>A continence assessment is required</p> <p>An assessment of comorbidities is required</p> <p>An osteoporosis risk assessment is required</p> <p>A vision assessment is required</p>	Agreed in round 1 (79% – 100%)	All included in assessment document (see table 2 below)

	<p>Mechanism (reasoning): staff understand the range of factors contributing to falls and are able to treat comorbidities more effectively</p> <p>Outcome: falls risk may be reduced and recovery enhanced in patients with dementia</p>	A medication review is required		
		An assessment of challenging behaviour is required		
		Formal assessments of gait and balance should be carried out by the Timed Up and Go (TUG) test [91]	No consensus after 2 rounds (54% & 62%)	
		All patients require attendance for a lying and standing blood pressure (BP)		

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Table 3: Compensating for the reduced ability of people with dementia to self-manage: CMOcs, consensus statements and outcomes				
	CMOc	Consensus statements	Outcome	Operationalisation
CMOc 4	Context: cognitive impairment may limit the ability of people with dementia to comply with instructions and form habits Mechanism (resource): staff tailor the intervention (e.g. exercises) to the circumstances of people with dementia and embed it in their existing routines Mechanism (reasoning): intervention becomes routine and habitual Outcome: more successful rehabilitation can be achieved	Interventions should be based on goals set by the patient and carer	Agreed in round 1 (86% - 100%)	<ul style="list-style-type: none"> • Goal Attainment Scaling [92] (GAS) implemented • Compass of Life [93] included to assist in goal identification
		Therapists should work with service users to minimise the risk of falling, as this may improve confidence and enable realistic risk taking.		Falls risk assessment included
		Therapists should help the service user and caregiver to develop a meaningful programme of activities		<ul style="list-style-type: none"> • Assessment records personal preferences, routines, and priorities • Therapists develop programme of meaningful activities based on information gathered
		Therapists should undertake observed activities with the service user to facilitate new learning		Included in assessment
		Exercise interventions should be informed by evidence based formats such as the Otago programme but tailored to the circumstances of people with dementia and embedded in their daily life	Agreed in round 2 (69%)	<ul style="list-style-type: none"> • During training, staff are encouraged to use evidence-based formats creatively • Training also includes advice on creating programmes and embedding them into routines • Coloured paper provided for embedding strategies
CMOc 5	Context: cognitive impairment may	The total number of physiotherapy sessions available in the first 3 months (including	No consensus	Implemented 2 assessment sessions and maximum 22 therapy

	<p>limit the ability of people with dementia to self-manage changes in circumstances</p> <p>Mechanism (resource): ongoing follow-up is provided</p> <p>Mechanism (reasoning): staff are able to reinforce previous interventions and adapt them to meet changing needs</p> <p>Outcome: improvements in mobility are sustained and new falls risks reduced</p>	<p>sessions delivered by a support worker) should be 16, 20 or 24</p> <p>The total number of occupational therapy (OT) sessions available in the first 3 months should be 3-4</p>	<p>after 2 rounds (31% - 62%)</p>	<p>sessions delivered by a mix of OT, physiotherapist and support worker</p>
CMOc 6	<p>Context: the burden on informal carers is high when caring for relatives or friends with dementia who are at risk of falling</p> <p>Mechanism (resource): carer support and education is provided</p> <p>Mechanism (reasoning): carer stress is reduced and skills increased</p> <p>Outcome: carers' capacity to assist with the delivery of interventions increases</p>	<p>Carer stress should be routinely assessed</p>	<p>Agreed in round 1 (93% - 100%)</p>	<ul style="list-style-type: none"> • Carer stress included in assessment • Training emphasises ensuring carers have capacity to be involved
		<p>Therapists should facilitate caregivers, family and friends to adopt a positive approach to risk</p>		<ul style="list-style-type: none"> • Training includes advice on carer education, including accepting 'positive risk'
		<p>Intervention staff should be able to provide basic carer education & support, referring to other agencies as needed</p>	<p>Agreed in round 2 (77%)</p>	<ul style="list-style-type: none"> • Carer education leaflets provided for dissemination [94, 95]

Table 4: Equipping the workforce with the necessary skills and information to care for people with dementia: CMOcs, consensus statements and outcomes				
	CMOc	Consensus statements	Outcome	Operationalisation
CMOc7	<p>Context: cognitive impairment may limit the ability of people with dementia to pass on information</p> <p>Mechanism (resource): staff use multiple sources of information including carers and direct observation</p> <p>Mechanism (reasoning): staff gain a better understanding of the individual</p> <p>Outcome: staff are able to provide appropriate, tailored care</p>	Assessment should involve multiple sources of information including information from carers	Agreed round 1 (93% – 100%)	The assessment (table 2) includes all of these components
		Assessment should include direct observation		
		A home hazard assessment should include a walk around the house to determine where actual falls have occurred and negotiate how these might be reduced		
CMOc8	<p>Context: current staff knowledge of, and attitudes to, dementia are variable</p> <p>Mechanism (resource): increased dementia training is provided</p> <p>Mechanism (reasoning): staff gain skills in and understanding of rehabilitation for people with dementia</p> <p>Outcome: staff ability and willingness to engage with people with dementia is enhanced</p>	Tier 2 training is required for intervention staff	Agreed round 2 (85%)	This was deemed unfeasible in the time available. A tailored training programme was developed, including items from tier 2 training.
		Training needs to include how to tailor an intervention for people with dementia.	Agreed round 1 (100%)	Training includes this
		Training needs to include advice on how to engage and motivate people with dementia.		Training includes this
		Training should include on the job role modelling		This was deemed unfeasible in the time available. Training delivered by therapists with experience in working with people with dementia, who

				were available remotely for advice.
CMOc9	<p>Context: care pathways are often unclear</p> <p>Mechanism (resource): a centralised, collaborative pathway is developed and disseminated</p> <p>Mechanism (reasoning): staff are better equipped to refer to the most appropriate services</p> <p>Outcome: service users receive better treatment</p>	The setting of the intervention should make use of existing pathways only when referral from the team deems it would be useful for the individual	Agreed round 1 (85.7% - 100%)	Assessment document includes tracking referrals that are decided by MDT
		A multidisciplinary team (MDT) meeting should be available if needed		<ul style="list-style-type: none"> MDT composition agreed as physiotherapist, OT, support workers and geriatrician, with a general nurse available where the team already included this. Community psychiatric nurse (CPN), social workers, reablement workers, old age psychiatrists and podiatrists accessible by referral. MDT meetings available at beginning and middle of intervention period.
		Therapists should offer service users information on assistive devices and facilitate delivery		This is flagged in the assessment document and available when needed