Cognitive–behavioural therapy-based intervention to reduce fear of falling in older people: therapy development and randomised controlled trial – the Strategies for Increasing Independence, Confidence and Energy (STRIDE) study

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Scientific summary

The STRIDE study

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Scientific summary

Background

Adverse consequences of falls are by no means limited to physical injury. Many older individuals, both fallers and non-fallers, suffer from a variety of adverse psychosocial difficulties related to falling including fear, anxiety, loss of confidence and impaired self-efficacy (in this context the self-perception of ability to walk safely without falling) resulting in activity avoidance, social isolation and increasing frailty. The umbrella term for these problems is 'fear of falling', a common and disabling problem in older individuals, found in around 50% of community-dwelling elders who fall, and up to 50% of those who have never fallen.

Current understanding of its management is limited. There is a small evidence base to support the use of some physical therapies to improve the syndrome, and promising early data from a few studies supporting the use of psychological therapies, in particular cognitive–behavioural therapy (CBT). The cognitive–behavioural quintet of a situation or practical problem (falls, declining mobility, social isolation), altered thinking and emotion, altered physical symptoms with behavioural change, and activity reduction and avoidance is paradigmatic for fear of falling, and offers the hope of a viable therapeutic option. Previous studies are hampered by poor documentation of power calculations, high dropout rates from intervention groups, group rather than individual therapy, lack of recording of quality-of-life measures and the absence of health-economic analysis.

There is a need for many more trained cognitive–behavioural therapists than are currently available; the development of a cognitive therapeutic package for the management of fear of falling that can be delivered routinely by non-specialist staff, such as health-care assistants (HCAs), is vital if this common condition is to be tackled effectively. CBT can be delivered by suitably trained non-psychotherapist staff, but to our knowledge this approach has not yet been attempted with HCAs.

It is important to collect longitudinal ethnographic data that help us to understand the social *processes* and *relationships* that lead any such intervention and trial to take a particular shape and direction. May and Finch (May C, Finch T. Implementing, embedding, and integrating practices: an outline of normalization process theory. *Sociology* 2009;**43**:535–54) previously developed a robust explanatory model of normalisation processes that defines psychological and sociological mechanisms of behaviour and action, which are important in the implementation of complex interventions. This approach is vital for the understanding and more widespread adoption of such an intervention and is a key component of our study. Our aim was to develop a novel CBT intervention (CBTi; Phase I) and then conduct a randomised controlled trial (RCT) of the individually tailored CBTi delivered by HCAs compared with control subjects to test its effectiveness in community-dwelling elders with fear of falling attending falls services (Phase II).

Objectives

Primary objectives

In Phase I, our objective was to develop a new CBTi for delivery by HCAs, aimed at reducing fear of falling in community-dwelling older adults who were attending falls services. In Phase II, our objective was to determine the effectiveness of the CBTi plus usual care compared with usual care alone in reducing fear of falling in community-dwelling older adults who were attending falls services.

Secondary objectives

Our secondary objectives were to:

(a) measure the impact of the intervention compared with control on fall and injury rates in the trial participants, and its impact on functional abilities
(b) measure the effectiveness of the intervention compared with control on anxiety and depression, quality of life, loneliness, social isolation and social participation
(c) investigate the acceptability of the intervention for patients, family members and professionals
(d) investigate further the professional and organisational factors that promote or inhibit the implementation and integration of the intervention
(e) measure the costs and outcomes of the intervention in this setting.

Methods

Phase I: cognitive–behavioural therapy intervention development

The development of the CBTi followed established principles in CBT but required in-depth exploration of the issues relevant to the client population and the development of a training approach that would equip non-specialist HCAs to deliver the CBTi to trial participants. The initial assessment interviews conducted to inform the intervention development opened up and challenged notions of the concept of 'fear of falling', uncovering both its heterogeneity (diversity of views and experiences) and complexity (in terms of associations between falls, appraisals of these, and related behaviours). In developing the intervention it was necessary to acknowledge and accommodate the importance of the network of comorbid physical complaints, interpersonal relationships and/or social isolation revealed as central to fear of falling. This was addressed by introducing individualised formulations, which added to the complexity of the intervention and created uncertainty over the feasibility of successful delivery of the CBTi by relatively inexperienced HCAs. To deliver the CBTi, HCAs needed to learn complex new skills. Although the training was generally felt to be adequate by the psychologists and the HCAs, further adaptation for a non-specialist audience is recommended. The HCAs' ability to embed and develop their CBTi skills was facilitated by individual and group supervision sessions and the HCAs' self-initiated peer support sessions.

Phase II: randomised controlled trial of cognitive–behavioural therapy intervention compared with usual care

Our study was a two-arm, parallel-group patient RCT of the novel CBTi plus usual multidisciplinary care compared with usual multidisciplinary care alone in community-dwelling older patients, who had a significant fear of falling and were attending multidisciplinary falls services. Significant fear of falling was defined by a Falls Efficacy Scale–International version (FES-I) score of > 23, with the main exclusions being cognitive impairment and need for alternative psychological treatment. The CBTi was delivered by three HCAs, with ongoing training, supervision and quality control from the supervising psychologists who developed the intervention. Individual 1-hour sessions were delivered almost exclusively in patients' homes for 8 weeks, with a top-up session at 6 months.

The study began as a single site study but, owing to recruitment difficulties, two further sites in our region were added, and, in addition, our power calculation was changed to reflect 80% power. A computer-generated blocked allocation was used to allocate patients in a 1 : 1 ratio to intervention and control groups. Randomisation was stratified by site, patient gender, baseline score on a numeric rating scale for pain when walking (0 vs. 1–10) and whether or not the patient had been referred for strength and balance training. The impact of missing data was assessed using an approach based on multiple imputation to impute missing values for the FES-I score at each of the follow-up time points, in those cases when the instrument was not completed at all or could not be scored. A further 'as treated' analysis took into account the number of CBTi sessions completed by each participant.

The primary outcome measure was change in fear of falling as assessed by the FES-I at 12 months. Secondary outcomes comprised falls, injuries, anxiety and depression [as measured by the Hospital Anxiety and Depression Scale (HADS)], quality of life, social participation and isolation measures and effects on physical function. The process evaluation began at study commencement and continued throughout the study and we also measured the costs and outcomes of the intervention in this setting.

Results of the randomised controlled trial

Four hundred and fifteen participants were recruited to the study, with 210 randomised to the CBTi and 205 to usual care groups. The groups were well matched in all respects at baseline, with mean FES-I scores of 40 in both groups. There was a significant difference between study arms in the primary outcome measure, with the estimated impact of the CBTi on FES-I scores at 12 months being a reduction in mean score of 4.02 [95% confidence interval (CI) 2.10 to 5.95].

The baseline standard deviation (SD) of FES-I was 9.37. The reduction in mean score of 4.02 can be expressed as a standardised effect size by dividing by this SD, yielding a point estimate of effect size of 0.43 and an interval estimate of between 0.22 and 0.64. Using a number of assumptions, the 'as treated' analysis estimated a mean reduction in FES-I scores of between 3.54 and 4.4. In addition, the single-item numerical fear of falling scale score fell significantly by –1.42 points (95% CI –1.87 to 1.07). There was a significant reduction in the HADS Depression score (–1; 95% CI –1.6 to –0.3) at 12 months in the CBTi group, but there were no differences in the other secondary outcome measures. There was no evidence that the CBTi was cost-effective.

The process evaluation found that the HCAs' delivery of the CBTi was evaluated positively by the psychologists, although some skills could be further developed. The delivery of the CBTi was shaped over time by the HCAs' growing experience of the client group, the complexity of fear of falling, and the tendency to revert to existing skill sets. The value of the CBTi for older people attending their falls services was recognised by some professional staff who were providing usual care. Participant engagement with, and understandings of, the CBTi varied, although participants valued their interactions with the HCAs and perceived a range of benefits from the CBTi including confidence and independence. The organisation and delivery of the CBTi in terms of the materials, session content, frequency and duration was generally acceptable to participants, although more flexibility over the follow-up session was suggested. There was a strong preference for delivery in the participant's home.

Discussion

Our novel CBTi delivered by HCAs, in addition to usual care in community-dwelling elders attending falls services, resulted in a significant reduction in fear of falling, as measured by the FES-I, compared with those receiving usual care alone. Similar improvements in FES-I scores were seen at 8 weeks and 6 months as at 12 months, despite the absence of intervention for the final 6 months of follow-up, and our study was powered on the basis of a 4-point reduction in FES-I scores. Although there are no definitions of minimal clinically significant changes in FES-I, or any other fear of falling measure, our FES-I effect size is among the highest reported, with recent randomised studies on interventions in fear of falling using the FES-I reporting significant decreases in scores ranging from 0.53 to 3.7.

There were significant improvements in HADS Depression scores in the CBTi group, an important finding given the high incidence of depression in older people, in particular those with fear of falling. There were no differences in social participation, loneliness, quality of life or physical function on a variety of measures; the fact that this client group suffers a multitude of comorbid psychological and physical difficulties that could not be addressed by the CBTi may explain the lack of responsiveness of these measures. There were no significant harms associated with the CBTi, with lower fall and fracture rates in the intervention group, although these were not statistically significant.

This study uncovered the extent to which older people's lives are curtailed by medical and psychosocial events. Although very few of these participants would have considered, or been eligible, for help from existing psychological services, their physical and psychosocial difficulties were marked. One of the key components of the STRIDE study was the delivery of the CBTi by HCAs, and this showed both the feasibility and effectiveness of using non-specialist staff with brief training to address these unmet needs. The fact that they were able to significantly reduce fear of falling indicates the potential for the UK NHS to address the comorbid needs of older adults without investing heavily in trained CBT therapists and clinical psychologists. This is not to underestimate the complexity involved in meeting these needs and we would emphasise the importance of recruitment, training and supervision of HCAs in any attempt to translate our findings into routine clinical practice.

Implications for health care

- We can be confident in concluding that our novel CBTi reduces fear of falling (as measured both by the FES-I and 11-point fear of falling rating scale) in community-dwelling older adults attending falls services. There is also evidence that the intervention reduced depression in such individuals. The fact that the intervention was successfully delivered by HCA-grade staff has important implications for its adoption into routine practice.
- When CBTi is integrated into existing services, it is important to ensure that the intervention is aligned with existing practices, as there is a potential for conflicting messages that can confuse patients and potentially confound the effects of the intervention. Public and patient involvement-based 'scripts' for introducing the CBTi to patients with fear of falling is important, as our process evaluation work showed clearly that clients conceptualise the intervention in various ways, which are highly dependent on how it is presented to them. This, in turn, profoundly influences engagement with the CBTi and the internalisation of its principles and techniques.
- Although our study did not set out to demonstrate which subset of individuals with fear of falling would benefit most from the intervention, it was clear that those with the lowest FES-I scores and those who least considered themselves to suffer from fear of falling were most likely to drop out of the study. This may have resource and clinical implications for targeting of patients for the CBTi.

Recommendations for research

- Our work shows clearly the heterogeneous nature of fear of falling and the importance of physical factors in its genesis and promotion. There are some small studies examining the role of a joint CBT and physical training approach in managing fear of falling, but these need to become larger scale, appropriately powered RCTs using findings such as ours to inform power calculations.
- Research into targeting of CBTi in older people with fear of falling will aid more rational use of scarce health service resources. As we discussed above, there is some evidence from our study of differential uptake and completion of CBTi but these factors need to be more explicitly explored.
- Previous studies have examined group CBT for fear of falling, whereas our intervention was individually based. From both individual effectiveness and resource perspectives it would be useful to trial a mix of approaches.
- This study highlighted the value of an embedded reflexive component to the design and conduct of any large trial. The presence of a qualitative component fostered a culture of reflection and open communication, which enabled the early identification of procedural and interpersonal issues and facilitated the conduct of the study.
- Stakeholders identified a number of potential service models for the future delivery of CBTi, for example in primary care and/or in generic CBT teams working into a range of departments in secondary care. Future research could explore the feasibility and cost-effectiveness of alternative service provision of CBTi.

Trial registration

This trial is registered as ISRCTN78396615.

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