RESEARCH PAPER

A posture and mobility training package for care home staff: results of a cluster randomised controlled feasibility trial (the PATCH trial)

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Abstract

Background: provision of care for care home residents with complex needs is challenging. Physiotherapy and activity interventions can improve well-being but are often time-limited and resource intensive. A sustainable approach is to enhance the confidence and skills of staff who provide care. This trial assessed the feasibility of undertaking a definitive evaluation of a posture and mobility training programme for care staff.
Design and setting: a cluster randomised controlled feasibility trial with embedded process evaluation. Ten care homes in Yorkshire, United Kingdom, were randomised (1:1) to the skilful care training package (SCTP) or usual care (UC).
Participants: residents who were not independently mobile.
Intervention: SCTP—delivered by physiotherapists to care staff.
Objectives and measurements: key objectives informed progression to a definitive trial. Recruitment, retention and intervention uptake were monitored. Data, collected by a blinded researcher, included pain, posture, mobility, hospitalisations and falls. This informed data collection feasibility and participant safety.
Results: a total of 348 residents were screened; 146 were registered (71 UC, 75 SCTP). Forty two were lost by 6 months, largely due to deaths. While data collection from proxy informants was good (>95% expected data), attrition meant that data completion rates did not meet target. Data collection from residents was poor due to high levels of dementia. Intervention uptake was variable—staff attendance at all sessions ranged from 12.5 to 65.8%. There were no safety concerns.
Conclusion: care home and resident recruitment are feasible, but refinement of data collection approaches and intervention delivery are needed for this trial and care home research more widely.

Keywords: *older people, long-term care, cluster randomised trial, posture and mobility, staff training*

Key points

- There is potential to improve residents' well-being by improving their posture and providing more opportunities for activity.
- Providing care staff with posture and mobility training may be a way of embedding good practice in daily care.

- Work is needed to tailor intervention approaches to improve uptake and sustainability of interventions in care homes.
- Alternative data collection approaches for residents with cognitive impairment are needed to ensure their voices are heard.

Introduction

Residents of care homes are among the frailest in our population with significant health and social care needs [1]. UK care homes provide long-term residential care [2,3] for residents who require assistance with activities of daily living and personal care, with some homes also providing nursing care. Typically, residents are aged over 80 years and have high levels of dependency and multiple morbidities—with a high prevalence of dementia (around 62%) [2,4]. In the United Kingdom, more than 400,000 older people live in 19,000 care homes [5], which vary in size from <20 to >100 beds. Length of stay is variable, with life expectancy shorter for nursing compared to residential home residents [6].

Physiotherapists working in care homes have observed the lack of opportunity for activity, as well as the poor posture of many residents [7]. Poor sitting position and unsatisfactory positioning in bed, along with unskilled movement assistance can lead to numerous health problems, including increased incidence of pressure sores, pain and loss of independence [8]. These factors can reduce opportunities to participate in social activities which can negatively impact on mood and self-esteem [9].

Physical activity can be improved in this population through targeted interventions, but these are often time-limited and resource-intensive [10]. A sustainable approach would be to enhance the confidence and skills of care home staff in postural awareness and facilitation of movement, with the aim of embedding skilled practice in routine care. Preliminary testing of the Skilful Care Training Package (SCTP)—developed by physiotherapists for care staff—suggested benefit [7], but this was a single-site pilot, reporting qualitative feedback; thus, a trial with embedded process evaluation was planned to explore the feasibility of conducting a definitive cluster randomised controlled trial (cRCT) [11].

A full description of the PATCH trial objectives can be found in Appendix 1. This paper focusses on objectives linked to the criteria for progression to a definitive cRCT: recruitment, intervention delivery, resident safety, resident data completeness and retention. Other objectives will be reported separately, including the detailed process evaluation exploring intervention fidelity and implementation.

Methods

The methods are described in full elsewhere [11], with methods relevant to this paper summarised below.

Design, setting and participants

A parallel-group feasibility cRCT was conducted in 10 care homes providing nursing or residential care for older people in the county of Yorkshire, UK, between May 2017 and September 2018.

Following screening of all residents, baseline data were collected for eligible residents (aged ≥65, life expectancy ≥3 months, not independently mobile) who provided consent or for whom consultee agreement was obtained [12].

Direct care staff were invited to provide proxy data for all participating residents and data about their own experiences of providing care.

Randomisation and allocation concealment

Following baseline assessment, homes were block-randomised with randomly selected block sizes to usual care (UC) or UC plus SCTP in a 1:1 ratio by a statistician independent of recruitment and data collection. An un-blinded researcher informed the care home manager of the allocation and arranged follow-up visits in an effort to maintain blinded outcome assessment.

Intervention

SCTP is a structured training intervention, delivered to groups of care home staff by physiotherapists utilising standardised practical exercises and presentations. The training aims to increase understanding of posture and skilful assistance of movement within a person-centred care framework, with the emphasis adapted to meet the needs of each home. Course materials are provided for reference.

For care homes allocated SCTP in this trial, trainers aimed to provide each member of direct care staff with 7.5-hour training, delivered over three 2.5-hour sessions. Repeat sessions were planned to maximise attendance.

Trainers provided data on the content and delivery of training sessions, attendance and assessed staff members' understanding of session content—their levels of engagement and demonstration of skills during training. Independent researcher observation of training sessions was also undertaken as part of the process evaluation.

Usual care

All homes continued to provide usual care, with data collected to describe staff mix and turnover, visiting professionals, training provision and any new care initiatives.

Outcomes and measurement

The following questionnaires were administered at baseline, 3- and 6-months post-randomisation by a blinded researcher.

Completed with residents:

- Iowa Pain Thermometer [13]

Table 1. Pre-specified progression criteria and observed results

Feasibility outcome	Pre-specified progression criteria			Feasibility trial observations
	Green (proceed)	Amber (revise)	Red (major revisions)	
Recruitment				
No. care homes recruited	**10**	8–9	<8	10
No. residents recruited (average)	≥**12**	8–11	Not specified	14.6
Intervention delivery				
Proportion staff attending all training sessions	≥65%	<65% and ≥50%	**<50%**	67/155 (43.2%)
Proportion staff attending ≥1 session	≥**75%**	<75% and ≥60%	<60%	119/155 (76.8%)
Data collection and follow-up				
Loss to follow-up (including deaths) at 6 months	≤25%	**>25% and ≤35%**	>35%	42/146 (28.8%)
No. residents with PAM-RC and EQ-5D-5L proxy data at 6-months	≥75%	**<75% and≥ 65%**	<65%	104/146 (71.2%)
Safety concerns around intervention delivery or trial processes	**None**	No major concerns	Major concerns	None

Bold indicates progression level (green, amber or red) met for each outcome.

- Six-item cognitive impairment test (6-CIT) [14]
- EuroQoL 5 Dimension, 5 Level questionnaire (EQ-5D-5L) [15]
- Postural assessment (study-specific observational tool).

    Completed with staff informants:

- Barthel Index of Activities of Daily Living (ADL) [16]
- Continuing Care Activity Measure (CCAM) [17]
- Functional Ambulation Classification (FAC) [18]
- Physical Activity and Mobility in Residential Care scale (PAM-RC) [19]
- EQ-5D-5L proxy.

The blinded researcher also reviewed participating residents' care notes to ascertain relevant co-morbidities, falls, hospitalisations, mortality and health service use.

Sample size

Although formal power calculations for feasibility studies are not usually undertaken, sufficient statistical power was ensured to assess potential efficacy on the proposed primary outcome for a definitive trial (PAM-RC). Ten care homes with an average of 12–15 residents provide 80% power to detect a minimum clinically important difference of 0.5 SD units between arms using a two-sided *t*-test with a 20% significance level, assuming loss to follow-up of 25% and an ICC of 0.03–0.05.

Statistical methods

Screening, recruitment, intervention delivery, data completion, safety outcomes and characteristics of residents, staff and care homes were summarised using descriptive statistics.

Analysis of resident outcomes included point estimates (based on cluster-level summaries) and a measure of variability (SD or range) by arm at each time point as well as confidence interval estimation (67, 80 and 95%).

To obtain a preliminary and non-definitive randomised comparison of SCTP with UC for the 6-month PAM-RC score, cluster-level point estimates were calculated for each arm and used to obtain a mean difference for the unadjusted intervention effect and corresponding 80% confidence interval (CI) [20]. The unpaired *t*-test was used to assess the null hypothesis of no difference in PAM-RC scores between the arms. Covariate adjustments were undertaken using a two-stage process. Expected numbers were computed (without the intervention effect) by fitting a regression model on individual-level data and compared with observed values for each cluster. The above methods for calculating the mean difference and CI were calculated but on the observed minus expected numbers.

A priori thresholds for specific outcomes were established to inform the feasibility of progressing to a definitive cRCT (Table 1).

Results

Resident recruitment and baseline characteristics

Figure 1 illustrates care home and resident screening, recruitment and follow-up.

Of the 10 participating care homes, seven provided nursing care (4 UC, 3 SCTP) and three were residential (1 UC, 2 SCTP). Care home baseline characteristics were similar between arms (Table 2).

Between May 2017 and January 2018, 348 residents were screened, assessed for eligibility ($N = 250$), consented ($N = 154$) and registered ($N = 146$). The most common reason for ineligibility was independent mobility (67/98–68.4%). Agreement was largely gained from personal consultees (51.3%) and nominated consultees (32.5%) due to high levels of cognitive impairment (198; 80.5% of those eligible, with known capacity status). Screening characteristics for those eligible were similar between participants and non-participants, aside from a slightly higher proportion of those without capacity participating (Appendix 2).

An average of 14.6 residents were recruited per home (range 8–22). Baseline characteristics were similar between
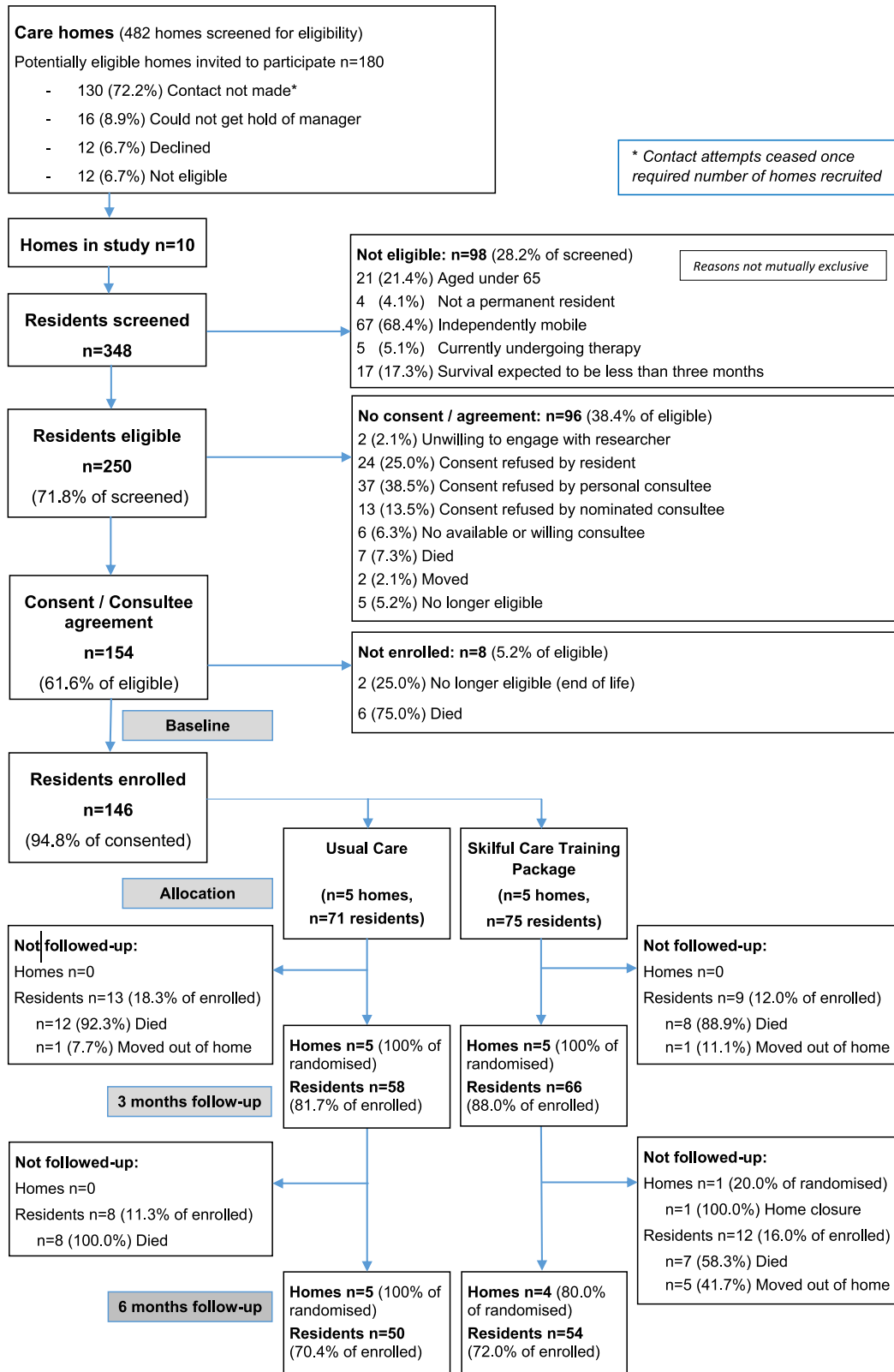
Figure 1. Care home and resident screening, recruitment and follow-up

Table 2. Care home and participating residents' baseline characteristics, by arm

	Usual care	SCTP	Overall
Care homes	**N = 5**	**N = 5**	**N = 10**
Number of beds in whole home			
Mean (SD)	48.4 (16.50)	44.6 (31.09)	46.5 (23.55)
Home/unit type[a]			
Nursing	4 (80.0%)	3 (60.0%)	7 (70.0%)
Residential only	1 (20.0%)	2 (40.0%)	3 (30.0%)
Size of participating home/unit (# beds)			
Nursing	39.3 (6.29)	31.3 (9.07)	35.9 (8.07)
Residential only	41.0 (—)	38.0 (11.31)	39.0 (8.19)
Home ownership			
Independent	1 (20.0%)	1 (20.0%)	2 (20.0%)
Care group	3 (60.0%)	1 (20.0%)	4 (40.0%)
Chain	1 (20.0%)	2 (40.0%)	3 (30.0%)
Chain (not for profit)	0 (0.0%)	1 (20.0%)	1 (10.0%)
Local authority	0 (0.0%)	0 (0.0%)	0 (0.0%)
Telemedicine facilities available			
Yes	3 (60.0%)	2 (40.0%)	5 (50.0%)
No	2 (40.0%)	3 (60.0%)	5 (50.0%)
Residents	**n = 71**	**n = 75**	**n = 146**
Age (years)			
Mean (SD)	84.5 (8.34)	87.4 (7.22)	86.0 (7.90)
Gender			
Female	47 (66.2%)	59 (78.7%)	106 (72.6%)
Male	24 (33.8%)	16 (21.3%)	40 (27.4%)
Ethnicity			
White	71 (100.0%)	73 (98.6%)	144 (99.3%)
Black	0 (0.0%)	0 (0.0%)	0 (0.0%)
Asian	0 (0.0%)	1 (1.4%)	1 (0.7%)
Not stated	0	1	1
Capacity			
Yes	11 (15.5%)	13 (17.3%)	24 (16.4%)
No	60 (84.5%)	62 (82.7%)	122 (83.6%)
Length of Stay in Care Home (months)			
Median (range)	31.0 (1, 232)	22.0 (1, 115)	25.0 (1, 232)
PAM-RC (Mean (SD))[b]			
Total score	4.5 (4.13)	4.3 (3.99)	4.4 (4.05)
Ability domain score	3.1 (2.56)	2.8 (2.23)	2.9 (2.39)
Activity domain score	1.5 (1.85)	1.5 (2.06)	1.5 (1.95)
FAC category[c]			
1—Non-functional Ambulation	51 (71.8%)	56 (74.7%)	107 (73.3%)
2—Dependent—Level II	6 (8.5%)	4 (5.3%)	10 (6.8%)
3—Dependent—Level I	6 (8.5%)	8 (10.7%)	14 (9.6%)
4—Dependent—Supervision	8 (11.3%)	7 (9.3%)	15 (10.3%)
Barthel total score[d]			
Mean (SD)	3.9 (3.92)	4.1 (4.59)	4.0 (4.26)
Missing	0	1	1
Pain score			
No pain	11 (28.9%)	18 (50.0%)	29 (39.2%)
Mild pain	13 (34.2%)	5 (13.9%)	18 (24.3%)
Moderate pain	9 (23.7%)	11 (30.6%)	20 (27.0%)
Severe pain	4 (10.5%)	1 (2.8%)	5 (6.8%)
Extreme pain	0 (0.0%)	1 (2.8%)	1 (1.4%)
Pain as bad as could be	1 (2.6%)	0 (0.0%)	1 (1.4%)
Missing	33	39	72
CCAM total score[e]			
Mean (SD)	52.5 (27.46)	56.2 (25.53)	54.4 (26.44)
Missing	4	2	6
Co-morbidities[f]			
0 co-morbidities	3 (4.2%)	0 (0.0%)	3 (2.1%)
1 co-morbidity	12 (16.9%)	6 (8.0%)	18 (12.3%)
2 co-morbidities	13 (18.3%)	6 (8.0%)	19 (13.0%)
3+ co-morbidities	43 (60.6%)	63 (84.0%)	106 (72.6%)

Notes: Number and percentage are presented unless otherwise stated. [a]There was one home in each arm where a single unit within a larger home providing both nursing and residential care participated in the trial (nursing unit in the UC arm and residential unit in the SCTP arm). [b]The PAM-RC contains 5 questions and the total score ranges from 0 to 21, with higher scores indicate greater physical activity. The questionnaire covers two domains: Ability and Activity. The Ability domain consists of two questions, and the total score ranges from 0 to 10. The Activity domain consists of three questions, and the total score ranges from 0 to 11. Individual scores have been assigned missing if any question is unanswered. [c]FAC scores of 5 or 6 made a resident ineligible for participation in the trial. [d]The Barthel Index is a 10 item questionnaire where the overall score ranges from 0 to 20. Higher scores indicate greater self-care ability. [e]The CCAM is a 16 item questionnaire where the overall score ranges from 16 to 112. Higher scores indicate greater motor function and mobility. [f]Number (percentage) of registered residents with a confirmed diagnosis of a condition is reported.

arms, although there was a slightly higher proportion of female residents and greater reporting of no or moderate pain in the SCTP arm. Participants had high levels of dependence, illustrated by a mean ADL score of 4.0 (SD 4.26) and a mean PAM-RC score of 4.4 (SD 4.05) (Table 2).

Intervention delivery and uptake

Four of the five intervention homes received the SCTP over three 2.5-hour sessions, while one home requested delivery over two 4-hour sessions. All homes received at least one of each planned training session, meaning that all content was covered at least once.

The proportion of staff attending at least one training session varied between homes from 53.6 to 92.6% (76.8% overall). Staff attending all sessions ranged from 12.5 to 65.8% (43.2% overall). Non-attendance was usually unexpected with reasons not provided.

The trainers assessed staff members' understanding of session content as good—with over 80% of attendees showing understanding of content, with most also able to demonstrate skills during practical sessions and discussions. Staff rated as not understanding certain concepts were mainly those who could not be assessed due to non-attendance or reluctance to participate.

A summary of attendance, delivery and engagement with the intervention can be found in Appendix 3.

Usual care (context)

The total number of staff per care home was greater in the UC arm; however, a lower proportion provided direct resident care. Approximately 60% were care staff in the UC homes, compared with 70–80% in the SCTP homes. All homes provided moving and handling, health and safety and safeguarding training, while 3/5 UC and 2/5 SCTP homes reported engagement in special initiatives—most often related to pressure care.

Attrition

One SCTP home closed shortly after the 3-month follow-up. Resident attrition was 42 (28.8%) at 6-months post-randomisation, with similar rates in each arm: 21 (29.6%) UC and 21 (28.0%) SCTP. Resident losses were mainly due to deaths, with a higher rate in UC (20/71–28.2%) compared with SCTP (15/75–20.0%). Baseline characteristics of those completing follow-up were similar to those who did not (Appendix 4). There were no resident withdrawals.

Data completion rates

Resident self-reported data

Pain Thermometer completion rates were low: 50.7% at baseline, 46.0% at 3-months and 43.3% at 6-months of those available for follow-up. Reasons for non-completion were related to residents' inability to engage, understand

or communicate, illustrating difficulties due to high levels of dementia. As a proportion of all residents registered as participants at baseline, completion rates at 6-months were only 30.8%. There were similarly low levels of resident completion of the EQ-5D-5L at 6 months (32.9% completed as a proportion of all participating residents).

The 6-CIT was only completed for 26 residents at baseline at the first six homes to participate in the trial. Based on this low completion rate and some observations of resident distress during completion, this assessment was discontinued.

Resident proxy data

Completion levels for proxy questionnaires were high: over 95% were fully complete for each outcome for those residents available for follow-up at each time point; however, data provision, when considered as a proportion of all residents registered at baseline, was lower, with 104/146 (71.2%) PAM-RC and EQ-5D-5L proxy questionnaires completed at 6 months.

Care notes data

Researcher collection of health care data was feasible from care home records; however, the way in which this data was documented varied between homes, and data collection was very time consuming.

Staff data

Staff completion of questionnaires about their own experiences of providing care was low at baseline (UC 41.2% and SCTP 53.1%) and declined across arms at each time point. Completion rates were similar between arms, with an overall return rate at 6 months of only 26.0%.

Outcomes and estimation

A decline in physical function was observed over time for residents followed-up, but there was no evidence that this decline was significant or differed between arms (Appendices 5 and 6). Although mean PAM-RC scores were slightly higher in the SCTP arm at 6 months, there was no preliminary evidence at the 20% significance level that the SCTP led to improvement on the PAM-RC (adjusted mean difference −0.50 80% CI (−1.12, 0.11)) (Appendix 7).

Adverse events

Falls, hospitalisations and deaths were monitored for registered residents and for all residents at each home on a regular basis throughout the trial. Whilst there were some differences between arms, numbers attending hospital following a fall were small and there were no concerns attributable to the intervention or trial processes (Appendix 8.)

Discussion

Generalisability and context

Baseline data illustrate the high level of disability and frailty in this population, with very low ADL and FAC scores. Nevertheless, this trial was suitable for a large proportion of residents (71.8% eligible), and uptake was good (61.6% of those eligible), comparing favourably with other care home trials [21–23]. Residents with and without capacity were included, with 83.6% participating following consultee agreement—reflecting the high levels of dementia in this setting, but also illustrating good engagement with consultees; of the eligible population, a higher proportion without capacity participated than those with capacity. That there were no requests to withdraw from the research suggests that participation was not seen by residents or their consultees as onerous or intrusive.

Limitations

Although potential efficacy was not seen, it is not possible to draw conclusions from this given the feasibility design and associated small sample size. Low data return rates from residents also affected the ability to observe any indicators of change in resident pain and quality of life. Both these factors mean it has not been possible to establish preferences for primary and secondary outcomes.

Maintenance of researcher blinding was difficult. At least one researcher was unblinded at 6 of the 10 participating care homes, mainly due to care staff revealing their home's allocation; however, the need to maintain continuity and engagement with residents and staff was deemed more important than introducing a new, blinded researcher to homes—which might disrupt good relationships.

Staff who attended training also provided proxy resident data. This has the potential to introduce bias; however, it was not considered appropriate to exclude staff members from training which was designed to benefit the whole home.

Interpretation and implications for future research

It is feasible to recruit care homes and residents to this cRCT although, as reported by other care home researchers [24,25], recruitment of both is time-intensive for researchers.

Resident follow-up is feasible for those remaining in the trial; however, high mortality rates have to be taken into account when considering primary outcomes and length of follow-up for a definitive RCT. Work is ongoing [26] to explore alternative designs to accommodate high attrition.

Resident data collection is feasible from proxy staff informants, but collection from residents is difficult due to cognitive impairment; thus, a future definitive RCT would need to rely on a proxy-reported primary outcome. However, it is important that residents' opinions are sought, and thus, collection of outcome data directly from residents needs to be approached in a way that allows greater participation from those with cognitive difficulties. In line with

recommendations from other researchers (for example [23,27]), it is suggested that alternative tools and methods specific to the care home resident population are developed.

Hospitalisation and death data were collected from care notes to allow timely monitoring of resident safety; however, collection of comprehensive health resource use data from care notes was time consuming. It may be more efficient to collect detailed health resource use data from other sources—for example, routinely available data from NHS Trusts. Work is ongoing to compare data collected from different sources.

The provision of training to all direct care staff was challenging, with attendance falling below the pre-specified criteria for an adequate intervention 'dose'; however, there was wide variability in uptake between homes, with one home meeting acceptable criteria and two others only just falling short of this threshold. This suggests that training is possible within certain contexts. These context-specific features are explored in the parallel process evaluation, reporting of which will include reasons for variable staff engagement (e.g. managers presenting training as mandatory) and suggestions for refining intervention content and delivery—for example, reducing duration by optimising content.

Data return rates from staff, where self-completion was required, were poor—a well-known challenge in this setting (for example [28,29]), which needs to be addressed by exploring alternative data collection methods.

Implications for progression

This trial has demonstrated that, whilst care home and resident recruitment is feasible, further refinement of data collection approaches and intervention delivery are needed before progressing to a definitive evaluation of SCTP.

Findings highlight wider challenges to undertaking trials in care homes, including difficulties with participant retention, uncertainties around appropriate resident outcome measures and variability in intervention uptake. Further work to establish alternative methodological approaches is planned.

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