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Author: Sian A. Koskela Fiona Jones Natasha Clarke Liezl Anderson Bernadette Kennedy Robert Grant Heather Gage Michael V. Hurley

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Title
Active Residents in Care Homes (ARCH): study protocol to investigate the implementation and outcomes of a whole-systems activity programme in residential care homes for older people.

Authors
Sian A Koskela\textsuperscript{a} *, Professor Fiona Jones\textsuperscript{a}, Natasha Clarke\textsuperscript{a}, Liezl Anderson\textsuperscript{b}, Bernadette Kennedy\textsuperscript{b}, Robert Grant\textsuperscript{a}, Professor Heather Gage\textsuperscript{c} and Professor Michael V Hurley\textsuperscript{a}

\textsuperscript{a} Faculty of Health Social Care & Education, Kingston University & St. George's University of London, London, UK

\textsuperscript{b} Integrated Falls and Bone Health Service, St George's Healthcare NHS Trust, London, UK

\textsuperscript{c} School of Economics, University of Surrey, Guildford, UK

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*Corresponding author. Address: Faculty of Health Social Care & Education, Kingston University & St. George's University of London, 2nd Floor Grosvenor Wing, St George's Hospital, Cranmer Terrace, London, SW17 0RE. Tel.: +44 (0)208 266 6190

Email address: Sian.Koskela@sgul.kingston.ac.uk
Abstract

Objectives
To evaluate the effectiveness, acceptability and costs of Active Residents in Care Homes, ARCH - a programme aiming to increase opportunities for activity in older care home residents.

Design
Feasibility study.

Setting
Residential care homes for older people.

Participants
10-15 residents, staff and family members will be recruited in each of the three participating care homes.

Intervention
ARCH is a 12-month ‘whole systems’ programme implemented by occupational therapists and physiotherapists. They will conduct a comprehensive assessment of each care home, considering the physical environment, working practices and organisation structure as well as residents’ individual needs, and recommend ways to address barriers and increase residents’ activity levels. The therapists will then work with staff to improve understanding of the issues, instigate training, environmental, organisational and working practice changes as necessary.

Main outcome measures
Residents’ activity levels, health and quality of life will be tested using several measures to see which are practicable and appropriate for this population in this context. This includes: Assessment of Physical Activity in Frail Older People; Pool Activity Level Checklist; Dementia Care Mapping observations; and EQ-5D-5L. Residents will be assessed prior to programme implementation then 4- and 12-months post-implementation. Semi-structured interviews will explore the experiences of residents, staff, family members and therapists.
Conclusions

Providing evidence of effectiveness and acceptability of ARCH, and documenting factors that impede/facilitate implementation will help us identify ways to enhance the care and quality of life of older people in residential care, and our understanding of how to implement them.

Trial Registration. ISRCTN24000891

Keywords

Older people; residential care homes; activity; quality of life; whole-systems programme
Background

In the United Kingdom (UK) 426,000 people are living in residential care, approximately 95% of whom are aged 65 or over[1]. This population has chronic, complex and multiple health needs and consequently high levels of dependency[2]. Care home residents have high levels of mobility problems, incontinence, cognitive impairment and behavioural symptoms, as well as multiple-morbidity[2], high rates of depression[3] and about 70% have dementia[4]. As more people live longer with chronic multi-morbidity, the demand for long-term care will increase. The associated rising costs of care will place further burden on already over-stretched health and social care budgets[5]. Consequently, it is essential to develop effective, efficient models of care that optimise resident's health and wellbeing.

Many care homes provide excellent care, but the care in some is perceived to be poor due to inadequate, depersonalising environments, negative staff attitudes and working practices, task-orientated approaches to care and a lack of opportunities for meaningful activity[6–8]. This can have a detrimental impact on residents' physical and mental wellbeing, undermining self-confidence, self-esteem, self-determination and personhood which are major determinants of a person's quality of life [6,9].

Meaningful activity refers to a broad range of activities – physical, social, cognitive, leisure activities – tailored to a person's needs and preferences and offering social, psychological, spiritual and physical benefits[10]. Engagement in meaningful activity has been shown to enhance health, wellbeing and quality of life for older people in care homes[7,8]. Residents' engagement in activity can also benefit those supporting residents, reducing carer burden and creating greater opportunities for positive engagement[7,12]. Focusing on activities that are meaningful to an individual can be an effective way to increase physical activity in older care home residents, the benefits of which include improved mobility, strength and flexibility[12], improved sleep,
concentration and memory[13] and reduced risk of falls[14]. New ways to increase physical activity are needed considering marginal impact of ‘traditional’ exercise interventions for older people in care homes[15].

The importance of meaningful activity provision in care homes is also recognised in UK policy and guidance[10] and is included within the UK regulatory and inspection frameworks[16]. Despite this increased recognition of the importance of activity, low levels of activity in care homes and subsequent detrimental effect on residents’ quality of life, has been documented in numerous studies[7,17,18]. Furthermore, studies have highlighted the complex and multi-level barriers to activity provision in residential settings[7,19–21] and there is recognition that care home staff need skilled advice and support to help them improve meaningful activity opportunities for residents[7].

Considering the complexity of these issues, evidence shows that interventions delivering effective person-centred activity programmes require a whole-systems approach that centres around the needs of the individual, but simultaneously addresses organisational and environmental barriers, whilst empowering and educating staff[7,20,21]. This implementation evidence has informed the development of the "Active Residents in Care Homes (ARCH)" programme, which is a complex, holistic activity programme incorporating staff training, individual assessments and support of residents and environmental change which is tailored to the needs of the care setting (see below for more detail). The programme was developed and piloted in a day-care setting, and has the potential to benefit participants, staff and family members/caregivers[22]. The aim of this feasibility study is to evaluate the ARCH programme in older person’s residential care settings.

Methods/Design

This feasibility study will investigate implementation of the ARCH programme in residential care homes and document barriers, facilitators and processes impacting on implementation. In line with Medical Research Council (MRC) guidance, quantitative and qualitative methods will be used to evaluate the efficacy, costs and acceptability to residents, families and staff of a whole-systems
programme designed to improve the health and quality of life of care home residents via increasing opportunities for participation in meaningful activity[23].

Setting and study participants

Three residential care homes in South London supporting adults aged 65 and over and with provision for people with dementia will be recruited to the study. Care homes will be recruited at 6 month intervals to enable assessments and implementation to take place in a timely manner. As this is a feasibility study designed to assess 1) if the programme works, 2) the most appropriate outcome measures and 3) the statistical characteristics of the outcomes measures to inform sample size calculation for a future trial, calculation of a formal sample size is not appropriate. Sample size calculations address situations where a hypothesis is to be definitively tested. However, following the advice of Teare and colleagues, who recommend 35 people in each arm for a clinical trial, a convenience sample of 10-15 residents will be recruited from each care home[24]. Residents who are unable to be cared for out of bed, to maintain a seated upright position or follow simple commands, due to severe cognitive impairment, will be excluded from the study. Ten-to-fifteen care staff and up to ten family members of residents will be recruited to participate in semi-structured interviews exploring their views of the programme. For inclusion in the study care staff should have been employed by the care home for a minimum of three months prior to each data collection point. The criteria have been developed with a study steering group and are sufficiently broad to encourage participation of staff with different levels of experience and who fulfil varied roles in the care home.

Intervention – the ARCH programme

ARCH is a whole-systems programme that aims to create a culture of activity within the care home so that residents are supported to engage in meaningful activity throughout the day and where activity is considered integral to care. It uses meaningful activity as a way of encouraging
physical activity and draws on theoretical models used widely in occupational therapy: the Model of Human Occupation[25]; the Person, Environment and Occupation model[26]; and theories of personhood and person-centred care in dementia[6].

ARCH uses a flexible framework which identifies areas of good practice and areas for enhancement in relation to activity. This ensures the programme is relevant and appropriate to the context of each care home. It is led by a multidisciplinary team of therapists specialising in older people and dementia care.

The programme will be conducted over 12 months and comprises an Implementation Phase lasting four months, and a Consolidation Phase lasting eight months [see Figure 1].

**Implementation Phase (0-4 months)**

A physiotherapist, occupational therapist and rehabilitation assistant work on-site to implement and integrate the programme into the care home. The main activities of this phase are:

- **Macro assessment of the care home environment**: a series of observations in the care home and interviews with residents, staff, managers and families to gain a comprehensive understanding of the physical, social and organisation environment of the home and residents’ needs, identifying barriers and facilitators to residents' participation in activity. The assessment findings are used to develop an implementation plan outlining a series of practical actions to enhance residents’ opportunities to engage in activity. This is shared and discussed with managers/staff who collaborate with the therapists to refine, agree and schedule a final plan.

- **Staff training**: 12 x two hour taught modules accompanied by experiential work-based learning and coaching by therapists to build the confidence and competence of staff to facilitate residents' engagement in activity. Modules are based on the core components of the ‘Wellbeing Wheel’ [see Figure 2] and modified to the context of each home. The ‘Wellbeing Wheel’ is the central programme tool and provides a framework for the assessment of individual residents’ needs related to activity and wellbeing and the
development of personalised activity plans to address these. Staff will give dedicated
support to at least one resident, acting as their 'activity champion', collaboratively
developing their personalised plan and helping them work towards it, ensuring it remains
meaningful and appropriate to their needs, abilities and interests.

- Environmental change: therapists work alongside managers, staff, residents and families to
  start implementing actions outlined in the agreed plan.

Consolidation phase (4-8 months)

The therapists then withdrawal from the home leaving the rehabilitation assistant to
support managers, staff, residents and families. Staff take responsibility for the programme once the
rehabilitation assistant leaves.

Table 1 provides some examples of how the programme might tackle barriers to activity
identified in the care homes.

Recruitment and consent

Residential care homes fulfilling inclusion criteria will be sent an introductory letter about
the study and invited to express their interest in participating. Interested care homes will be
provided with an information sheet and meetings arranged with the care home managers/owners.
This will provide an opportunity to assess the care home's suitability, discuss the study in detail and
outline the commitment required from the care home. Criteria used to indicate suitability, includes:
desire of owners/managers to participate; ability to work to study timeframe; home size and
location; physical and organisational environment; and range of resident needs. Information gained
at these meetings will be considered by the study team in relation to suitability criteria and one care
home will be selected to take part. A partnership agreement, outlining the roles and responsibilities
of the care home, research team and therapists will be signed by the care home manager/owner
recording their agreement to participate. This process will be repeated six and twelve months later
to recruit a further two care homes. Diversity between settings will be an additional consideration in
the selection of care homes two and three in order to explore how the programme works in varied environments.

Recruitment of residents will comprise a multi-staged process designed to maximise opportunities for participation and minimise feelings of pressure to take part[27,28]. All residents will be given information about the study in a suitable format (e.g. large print or audio). Informal meetings will then be held with residents and researchers to explain the study further. Following this, researchers will visit all residents identified by the care home manager as meeting inclusion criteria to discuss the study, answer questions and assess their capacity to consent following Mental Capacity Act (MCA) 2005 guidance[29]. For residents with capacity to consent, the researchers will provide more detailed information in a suitable format, allow them at least 48 hours to consider participation and then follow up in person to find out their decision. Those residents agreeing to take part will be asked to provide written consent. For residents without capacity to consent, assent will be sought via a consultee following MCA 2005 guidance[29].

Residents will have diverse, complex and changing needs and consequently their capacity to consent and willingness and/or ability to participate in the study may fluctuate. This study will therefore use a process consent approach assessing the willingness of residents to participate, and their capacity to consent, on an occasion-by-occasion basis, via verbal questioning and by paying attention to body language, behaviours and verbal signs which might indicate disengagement and unwillingness[30]. If at any point during the study it is felt that the resident may not have capacity to consent then consultee assent will be used.

Recruitment of family members and care staff will involve provision of introductory information about the study and invitation to meet with researchers. Here they will be asked to consider participation in the study and provided with a participant information sheet. For those willing to participate written informed consent will be gained.

Data collection
Baseline data will be collected from consenting residents in each care home before the programme is implemented. Follow-up data will be collected four months and 12 months after implementation [see Figure 3]. Semi-structured Interviews with care staff and family members will take place at these time points to explore acceptability and experiences of the programme.

**Outcome Measures**

The most appropriate outcome measures for assessing activity levels, health and quality of life in older care home residents (with and without cognitive impairment) are unclear. This feasibility study will test several measures to see which are practicable and appropriate for this population in this context.

*Assessment of Physical Activity in Frail Older People*[31] is an interview administered subjective assessment of the frequency, duration, intensity and type of physical activity over a 24 hour period. It was designed and validated specifically for frail older people with and without mild to moderate cognitive impairment and focuses on the main physical activity domains relevant to this group including walking, standing, time on feet indoors and outdoors, sitting and lying.

*Pool Activity Level Checklist (PAL)*[32] is a carer-rated instrument that identifies the level of cognitive ability an individual has to engage in activity. PAL covers nine everyday activities: bathing/washing; getting dressed; eating; contact with others; group work skills; communication skills; practical activities; use of objects; and looking at a newspaper/magazine. There are four activity levels: planned, exploratory, sensory and reflex. The checklist demonstrates adequate validity and reliability when used with older people with dementia*[33]*.

*Dementia care mapping (DCM)*[34] is a set of structured observational tools used in formal dementia care settings exploring quality of life and quality of care from the perspective of the
person with dementia. DCM also captures information about levels and types of activity and is grounded in the theoretical perspective of a person-centred approach to care[6]. It has been used in numerous research studies, including evaluations of interventions, [35] and concurrent validity, test-retest reliability and internal consistency have been demonstrated[36,37].

EQ-5D-5L[38] measures health-related quality of life (HRQOL) using questions in five areas, plus the EuroQol Visual Analogue Scale, and is administered as a self-completion questionnaire or via interview. It is commonly used to measure HRQOL, has been successfully used in care home populations[15] and is a feasible and reliable measure in people with dementia[39]. The scale incorporates a health utility index for calculation of quality adjusted life years (QALYs), which will be used for preliminary cost-effectiveness assessments.

Residents' care plans and care home records will be reviewed using bespoke forms to collect information on resident's health status, medication usage and health service utilisation. Basic demographic data (e.g. age, sex, ethnicity), fall rates and information about any adverse events arising from the programme will also be collected.

Interviews

Semi-structured interviews will explore the acceptability of the programme with residents, staff, family members and the therapists delivering the intervention. Their views and experiences of the impact of the programme and implementation process will be explored. For some residents participating in an interview may be a physically and cognitively demanding activity, therefore interviews will be conducted with flexibility and sensitivity, drawing from best practice outlined in existing literature[27,28,30].

Ethical approval and considerations
Ethical approval was gained from the National Research Ethics Service (NRES) Committee London - South East in September 2014 (ref 14/LO/1329). The trial is registered as ISRCTN24000891. A key ethical consideration in the design of this study was the development of an appropriate strategy for facilitating the inclusion of older care home residents with diverse, complex and changing needs, whose capacity to consent may be compromised or fluctuating. The study team drew on the expertise of researchers working in the field, from recommendations for good practice outlined in the existing literature[27,30] as well as legal and regulatory frameworks[29,40]. Traditional competency based informed consent procedures and proxy consent approaches were felt insufficient, exclusionary and not in keeping with the person-centred ethos of the programme. Therefore a process consent approach was agreed which views consent as a continuous process based on the on the development of meaningful relationships and allowing flexibility and responsiveness to the context and people involved[28,30].

Analysis

Quantitative analysis. Outcomes at baseline and follow-up assessments will be summarised using descriptive statistics. Primary analyses will be by intention to treat, at p<0.05 significance level. Confidence intervals and p-values will be calculated using nonparametric bootstrap methods for outcome measures exhibiting floor/ceiling effects. Rates of attrition, non-adherence and missing data will be detailed, along with reasons where possible. Potential predictors of adoption and adherence will be analysed where possible using logistic regression and proportional hazards (Cox) regression respectively, to highlight which outcomes are most valuable for a future trial and to tentatively explore whether any subgroups benefit more than others. Recommendations for minimum clinically important difference will be explored by anchor or consensus methods, which will inform sample size for future trials[41].
Qualitative analysis. Semi-structured interviews will be audio-recorded, transcribed and anonymised. Thematic analysis will be used to analyse data from interviews and observations of researchers because it is a well suited approach often used in the preliminary evaluation of a new healthcare intervention[42]. A qualitative data analysis software package NVivo 10 (2010, QSR International Pty Ltd, www.qsrinternational.com) will be used to manage and summarise the data. Within-care home and across-care home comparisons will be made to evaluate the similarities, differences, processes and interactions critical in the implementation and integration of the programme into practice.

Health economic analysis

The main measure of effectiveness for the economic analysis is the EQ-5D-5L, from which Quality Adjusted Life Years (QALYs) gained are calculated. Since the programme may affect residents' health and wellbeing, we will gather data on resident use of health services, comparing baseline and intervention phases. Nationally validated unit costs[43] will be used to calculate the costs of the care staff incurred and the full cost of delivering the programme will be calculated, drawing from therapist timesheets and records of expenditure. A preliminary analysis of costs and effects will be undertaken, to explore the incremental benefits arising from the expenditure on the programme, compared to usual care (no intervention), and the likely value of conducting a full cost-effectiveness analysis in any future trial.

Discussion

This protocol describes a study that will evaluate ARCH – a programme that takes a whole-systems approach to increasing activity engagement in older residents in care homes. The study will provide information about the programme’s efficacy, costs, and acceptability and, very importantly, the barriers and facilitators required to enable implementation in a residential care setting. The methods are based on the MRC framework for developing and evaluating complex interventions[23]
and draw from other work in this field[15,20,21]. Delivering the programme in three different settings will advance understanding of how local contextual factors may affect success. Gaining the views and experiences of a variety of individuals involved will help to ensure future development of the programme remains relevant to their needs. Data will be collected using a range of measures thereby helping to improve understandings of the practicability and acceptability of such measures in this setting and inform future research in this field.

Ethical approval: NRES Committee London – South East (ref 14/LO/1329).

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Conflict of interest: None declared.

References


Kingsley Publishers; 2012.


Table 1: examples of activity barriers and recommendations for improvement

<table>
<thead>
<tr>
<th>Assessment area</th>
<th>Example barrier</th>
<th>Example recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical environment</td>
<td>Arrangement of chairs in a large circle around the lounge does not support socialisation between residents.</td>
<td>Arrange chairs in small clusters, ideally positioned around key focal points e.g. fish tank or TV.</td>
</tr>
<tr>
<td></td>
<td>Lack of accessible objects on display to offer stimulation and encourage activity.</td>
<td>Place objects of interest around the room, ensuring they are visible and accessible, to encourage activity e.g. games, photos, sensory objects and rummage boxes filled with items.</td>
</tr>
<tr>
<td></td>
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<td></td>
</tr>
<tr>
<td>Organisational environment</td>
<td>Staff report feeling overstretched and not having enough time for activities.</td>
<td>The therapy team consider the whole organisational culture of the care home and propose strategies to streamline working practices to allow more time for activities e.g. greater structuring of non-care staff time, rationalisation of staff documentation processes etc.</td>
</tr>
<tr>
<td></td>
<td>Limited time for handover meetings and infrequent staff meetings results in limited opportunities for discussion of residents' needs or consideration of activity in care planning.</td>
<td>Reorganisation of staff handover and communication system. Establishment of monthly staff meetings where activity planning is prioritised.</td>
</tr>
<tr>
<td>Staff practice</td>
<td>Staff lack knowledge and confidence in supporting residents with more advanced dementia to engage with activities, resulting in these residents spending large portions of the day unstimulated and sedentary.</td>
<td>Training and on floor demonstration by therapists to enhance knowledge and skills in this area including: guidance to use the Pool Activity Level Checklist to support tailoring of activities to resident needs, the establishment of sensory movement groups and the prioritisation of time for one-to-one between staff and residents.</td>
</tr>
<tr>
<td>Resident wellbeing &amp; activity levels</td>
<td>The multi-factorial influences on residents’ activity levels and wellbeing are not always considered by staff, for example the effects of medication or sleep patterns.</td>
<td>Though training staff will gain greater knowledge of the complex interrelated factors affecting residents’ participation in activities. Training will be centred on the wellbeing wheel tool which acts as a thinking tool to help staff integrate their knowledge of residents and to develop solutions to overcome individual barriers to meaningful activity.</td>
</tr>
</tbody>
</table>

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**Figure 1: ARCH programme 12 month implementation process.**

- **Macro assessment:**
  - Observations/interviews to understand the care home environment and identify barriers/facilitators to activity.
  - Development and agreement of implementation plan with care home.

- **Supported continuation:**
  - Senior therapists leave and Rehabilitation Assistant assumes a primary role:
    - Supporting staff to continue to apply learning and encourage residents’ engagement in activity.
    - Helping to implement remaining actions from the implementation plan and identify future areas for development.
    - Supporting managers to devise strategies for ensuring programme sustainability.

- **Staff training:**
  - 12 x 2hr training sessions to address activity and wellbeing in the context of each care home.
  - Staff supported to apply learning to work context and develop residents’ activity plans.

- **Environmental change:**
  - Staff supported to implement actions outlined in plan for each care home.
Figure 2: Wellbeing Wheel Outline

Life history
Communication
Wellbeing/illbeing
Meaningful activities
Mobility
Sensory impairments
Medical conditions
Medication
Sleep and arousal patterns
G
Activity - Wellbeing
Risk of falls and fractures
Environment
Nutrition and hydration
Continence
Medication
Environment

1: No concerns/much improved/meeting needs
2: Requires monitoring/room for improvement/some needs met
3: Prioritise intervention/high risk
Figure 3: Study design and time frame.

Research Site 1
- T1* = baseline data collection
- T2† = 4 month follow up
- T3‡ = 12 month follow up

Research Site 2
- Implementation & delivery of ARCH

Research Site 3
- Implementation & delivery of ARCH

* T1 = baseline data collection
† T2 = 4 month follow up
‡ T3 = 12 month follow up