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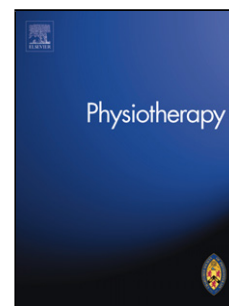
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1 **Title**

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

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17 **Abstract**

18

19 Objectives

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

22 Design

23 Feasibility study.

24 Setting

25 Residential care homes for older people.

26 Participants

27 10-15 residents, staff and family members will be recruited in each of the three participating care
28 homes.

29 Intervention

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

36 Main outcome measures

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

43

44 Conclusions

45 Providing evidence of effectiveness and acceptability of ARCH, and documenting factors that

46 impede/facilitate implementation will help us identify ways to enhance the care and quality of life of

47 older people in residential care, and our understanding of how to implement them.

48

49 Trial Registration. ISRCTN24000891

50 **Keywords**

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

52

53

53 Background

54

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

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

70 Meaningful activity refers to a broad range of activities – physical, social, cognitive, leisure
71 activities – tailored to a person's needs and preferences and offering social, psychological, spiritual
72 and physical benefits[10]. Engagement in meaningful activity has been shown to enhance health,
73 wellbeing and quality of life for older people in care homes[7,8]. Residents' engagement in activity
74 can also benefit those supporting residents, reducing carer burden and creating greater
75 opportunities for positive engagement[7,12]. Focusing on activities that are meaningful to an
76 individual can be an effective way to increase physical activity in older care home residents, the
77 benefits of which include improved mobility, strength and flexibility[12], improved sleep,

78 concentration and memory[13] and reduced risk of falls[14]. New ways to increase physical activity
79 are needed considering marginal impact of 'traditional' exercise interventions for older people in
80 care homes[15].

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

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

98 **Methods/Design**

99 This feasibility study will investigate implementation of the ARCH programme in residential
100 care homes and document barriers, facilitators and processes impacting on implementation. In line
101 with Medical Research Council (MRC) guidance, quantitative and qualitative methods will be used to
102 evaluate the efficacy, costs and acceptability to residents, families and staff of a whole-systems

103 programme designed to improve the health and quality of life of care home residents via increasing
104 opportunities for participation in meaningful activity[23].

105

106 Setting and study participants

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

124

125 Intervention – the ARCH programme

126 ARCH is a whole-systems programme that aims to create a culture of activity within the care
127 home so that residents are supported to engage in meaningful activity throughout the day and
128 where activity is considered integral to care. It uses meaningful activity as a way of encouraging

129 physical activity and draws on theoretical models used widely in occupational therapy: the Model of
130 Human Occupation[25]; the Person, Environment and Occupation model[26]; and theories of
131 personhood and person-centred care in dementia[6].

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

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

138 Implementation Phase (0-4 months)

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

- 141 • Macro assessment of the care home environment: a series of observations in the care home
142 and interviews with residents, staff, managers and families to gain a comprehensive
143 understanding of the physical, social and organisation environment of the home and
144 residents' needs, identifying barriers and facilitators to resident's participation in activity.
145 The assessment findings are used to develop an implementation plan outlining a series of
146 practical actions to enhance residents' opportunities to engage in activity. This is shared and
147 discussed with managers/staff who collaborate with the therapists to refine, agree and
148 schedule a final plan.
- 149 • Staff training: 12 x two hour taught modules accompanied by experiential work-based
150 learning and coaching by therapists to build the confidence and competence of staff to
151 facilitate residents' engagement in activity. Modules are based on the core components of
152 the 'Wellbeing Wheel' [see Figure 2] and modified to the context of each home. The
153 'Wellbeing Wheel' is the central programme tool and provides a framework for the
154 assessment of individual residents' needs related to activity and wellbeing and the

155 development of personalised activity plans to address these. Staff will give dedicated
156 support to at least one resident, acting as their 'activity champion', collaboratively
157 developing their personalised plan and helping them work towards it, ensuring it remains
158 meaningful and appropriate to their needs, abilities and interests.

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

161 Consolidation phase (4-8 months)

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

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

167

168 Recruitment and consent

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

181 the selection of care homes two and three in order to explore how the programme works in varied
182 environments.

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

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

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

205

206 Data collection

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

211

212 Outcome Measures

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

217

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

223

224 Pool Activity Level Checklist (PAL)[32] is a carer-rated instrument that identifies the level of
225 cognitive ability an individual has to engage in activity. PAL covers nine everyday activities:

226 bathing/washing; getting dressed; eating; contact with others; group work skills; communication
227 skills; practical activities; use of objects; and looking at a newspaper/magazine. There are four

228 activity levels: planned, exploratory, sensory and reflex. The checklist demonstrates adequate
229 validity and reliability when used with older people with dementia[33].

230

231 Dementia care mapping (DCM)[34] is a set of structured observational tools used in formal
232 dementia care settings exploring quality of life and quality of care from the perspective of the

233 person with dementia. DCM also captures information about levels and types of activity and is
234 grounded in the theoretical perspective of a person-centred approach to care[6]. It has been used in
235 numerous research studies, including evaluations of interventions, [35] and concurrent validity, test-
236 retest reliability and internal consistency have been demonstrated[36,37].

237

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

244

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

249

250 Interviews

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

257

258 Ethical approval and considerations

259 Ethical approval was gained from the National Research Ethics Service (NRES) Committee
260 London - South East in September 2014 (ref 14/LO/1329). The trial is registered as ISRCTN24000891.

261 A key ethical consideration in the design of this study was the development of an
262 appropriate strategy for facilitating the inclusion of older care home residents with diverse, complex
263 and changing needs, whose capacity to consent may be compromised or fluctuating. The study team
264 drew on the expertise of researchers working in the field, from recommendations for good practice
265 outlined in the existing literature[27,30] as well as legal and regulatory frameworks[29,40].
266 Traditional competency based informed consent procedures and proxy consent approaches were
267 felt insufficient, exclusionary and not in keeping with the person-centred ethos of the programme.
268 Therefore a process consent approach was agreed which views consent as a continuous process
269 based on the on the development of meaningful relationships and allowing flexibility and
270 responsiveness to the context and people involved[28,30].

271

272 Analysis

273 Quantitative analysis. Outcomes at baseline and follow-up assessments will be summarised
274 using descriptive statistics. Primary analyses will be by intention to treat, at $p < 0.05$ significance level.
275 Confidence intervals and p-values will be calculated using nonparametric bootstrap methods for
276 outcome measures exhibiting floor/ceiling effects. Rates of attrition, non-adherence and missing
277 data will be detailed, along with reasons where possible. Potential predictors of adoption and
278 adherence will be analysed where possible using logistic regression and proportional hazards (Cox)
279 regression respectively, to highlight which outcomes are most valuable for a future trial and to
280 tentatively explore whether any subgroups benefit more than others. Recommendations for
281 minimum clinically important difference will be explored by anchor or consensus methods, which
282 will inform sample size for future trials[41].

283

284 Qualitative analysis. Semi-structured interviews will be audio-recorded, transcribed and
285 anonymised. Thematic analysis will be used to analyse data from interviews and observations of
286 researchers because it is a well suited approach often used in the preliminary evaluation of a new
287 healthcare intervention[42]. A qualitative data analysis software package NVivo 10 (2010, QSR
288 International Pty Ltd, www.qsrinternational.com) will be used to manage and summarise the data.
289 Within-care home and across-care home comparisons will be made to evaluate the similarities,
290 differences, processes and interactions critical in the implementation and integration of the
291 programme into practice.

292

293 Health economic analysis

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

303 Discussion

304 This protocol describes a study that will evaluate ARCH – a programme that takes a whole-
305 systems approach to increasing activity engagement in older residents in care homes. The study will
306 provide information about the programme's efficacy, costs, and acceptability and, very importantly,
307 the barriers and facilitators required to enable implementation in a residential care setting. The
308 methods are based on the MRC framework for developing and evaluating complex interventions[23]

309 and draw from other work in this field[15,20,21]. Delivering the programme in three different
310 settings will advance understanding of how local contextual factors may affect success. Gaining the
311 views and experiences of a variety of individuals involved will help to ensure future development of
312 the programme remains relevant to their needs. Data will be collected using a range of measures
313 thereby helping to improve understandings of the practicability and acceptability of such measures
314 in this setting and inform future research in this field.

315

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319 Conflict of interest: None declared.

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463 **Table 1: examples of activity barriers and recommendations for improvement**

Assessment area	Example barrier	Example recommendations
Physical environment	<ul style="list-style-type: none"> • Arrangement of chairs in a large circle around the lounge does not support socialisation between residents. • Lack of accessible objects on display to offer stimulation and encourage activity. 	<ul style="list-style-type: none"> • Arrange chairs in small clusters, ideally positioned around key focal points e.g. fish tank or TV. • 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.
Organisational environment	<ul style="list-style-type: none"> • Staff report feeling overstretched and not having enough time for activities. • 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. 	<ul style="list-style-type: none"> • 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. • Reorganisation of staff handover and communication system. Establishment of monthly staff meetings where activity planning is prioritised.
Staff practice	<ul style="list-style-type: none"> • 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. 	<ul style="list-style-type: none"> • 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.
Resident wellbeing & activity levels	<ul style="list-style-type: none"> • 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. 	<ul style="list-style-type: none"> • Through 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.

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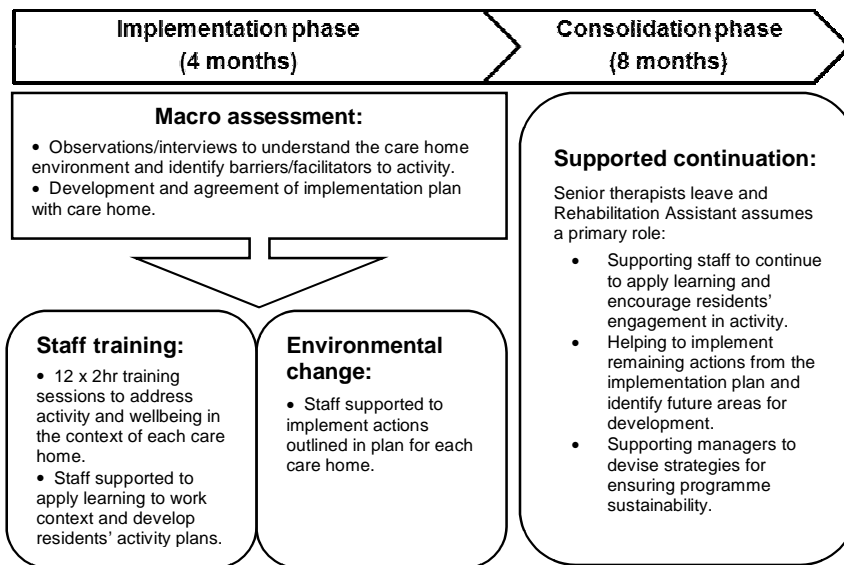
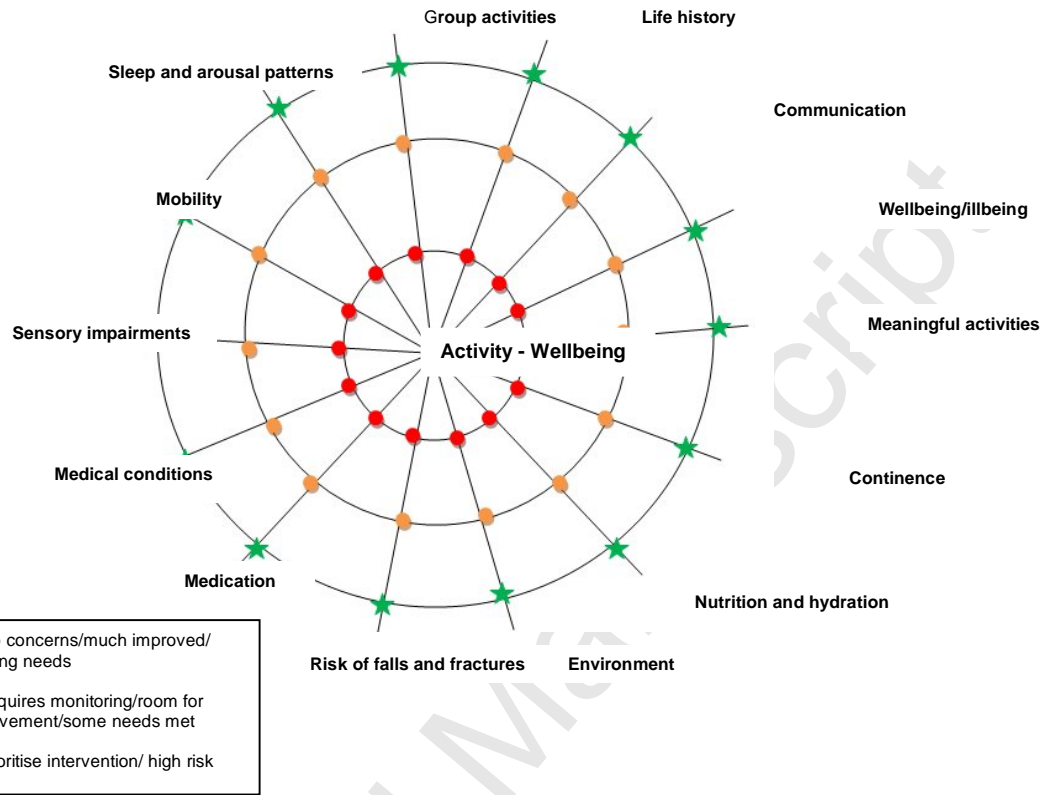


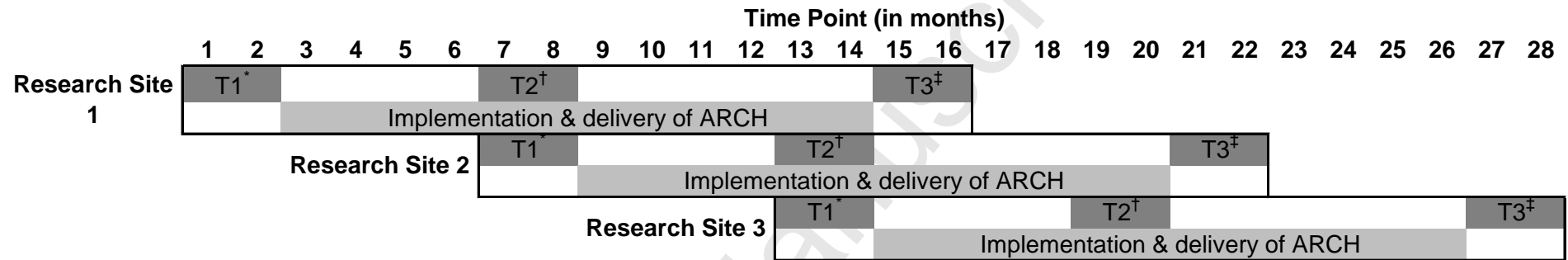
Figure 1: ARCH programme 12 month implementation process.

483 Figure 2: Wellbeing Wheel Outline
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Figure 3: Study design and time frame.



* T1 = baseline data collection

† T2 = 4 month follow up

‡ T3 = 12 month follow up