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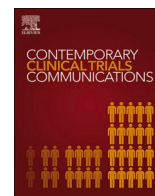
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## Resource assessment in trials undertaken in residential care homes: Experiences from the Australian MIDDEL cluster randomised controlled trial research team

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### ABSTRACT

**Background:** The resources involved in delivering a clinical trial in residential aged care facilities (RACFs) are significant and the success of a trial is dependent upon adequate planning, including appropriate timelines for each component of the study and the required budget. This paper describes process and resource assessment during recruitment, collection of outcome measures and intervention delivery, and presents learnings and considerations for conducting trials in RACFs with people living with dementia.

**Methods:** Data were collected across 24 clusters in 12 RACFs over 18 months during a cluster randomised controlled trial which was testing the effectiveness of music interventions in people living with dementia. Data were collected on resources required for recruitment and assessment of baseline data, as well as reasons for participant non-attendance at the interventions.

**Results:** Time between contacting next of kin and receiving formal consent often exceeded 45 days. The ratio of time between direct and indirect research activity was approximately 1:2. Participant intervention adherence is at risk from unplanned RACF lockdowns and reasons for non-attendance include those both related directly to the participant and to staff resources, scheduling or other practical considerations.

**Conclusions:** Research planning should focus on building relationships with RACF staff and resident families, factor in adequate time for recruitment in the study timeline and consider budgeting for backfill of RACF staff during data collection phases to expedite the process and ensure adherence to study protocol timelines.

**Trial registration Australian and New Zealand Clinical Trial Registry: ANZCTR12618000156280, 1/02/2018, <http://anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12618000156280>: A**

### 1. Background

Conducting high quality research in residential aged care facilities (RACF) can be time consuming, difficult, challenging and expensive [1]. A successful trial is one that recruits to time and collects comprehensive quality data within the originally agreed budget. Despite increases in research within RACFs, there is a paucity of literature that reports on resource use that could be beneficial for future researchers [1].

Our review of non-pharmacological intervention feasibility studies of people living in RACFs found no systematic study of resource use. Two research teams described experiences of conducting clinical trials within

RACFs and found that when it comes to recruitment, older people were more reluctant to participate in research and required more time and resources compared with younger people [2,3]. RACF residents were reluctant to consent to participate because they had difficulty comprehending what was being asked of them, while families declined to enrol residents for fear the assessments and interventions might deplete residents' existing energy levels.

Efficient collection of data from residents and staff can be difficult especially during busy periods of the day [2]. Researchers experienced long waiting periods for residents to finish personal care activities and data collection was often postponed at the last moment if the resident

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did not feel well, had an unexpected visitor, or simply did not feel like participating at that time. RACF staff view research as a low priority and do not always have time to commit to research alongside their busy schedules [2,3]. It was recommended that researchers invest time understanding RACF structures, including how staff are impacted by intra and inter-shift dynamics [3]. Researchers should invest time in developing relationships with the care staff and work around times that best suit the RACF staff availability [3].

Recent research found that barriers to care staff participation also stem from staffs' lack of belief in the potential for the tested interventions to have benefit or effect [4]. Overcoming such barriers by building strong partnerships with RACFs is likely to increase the chances of a successful trial delivery [5].

The MIDDEL randomised controlled trial [6] was designed to test the effectiveness of group music therapy and recreational choir singing on the symptoms of depression and dementia of 1000 people living in RACFs across several countries. In 2017, the Australian MIDDEL team were the first to secure funding and commenced data collection in May 2018. With other countries not securing funding until two years later, the Australian team was afforded the opportunity to identify management and resource issues that may not be gleaned from a small pilot study. We recognised that our learnings would be valuable to share to other researchers planning studies within RACFs contexts. We systematically collected resource and management data on recruitment, assessment, and intervention over 2-years for 24 clusters within 12 RACFs with total enrolment of 397 participants and provide recommendations for planning of future studies in RACF settings.

## 2. Methods

### 2.1. Our study posed the following resource assessment questions

#### 2.1.1. Resource assessment: recruitment

- (1) What is the mean number of attempts to contact the guardian/next of kin (NOK) before initial contact is reached?
- (2) What is the mean number of days between initial contact with NOK and receiving verbal consent, formal written consent, or a decline to consent for study participation?
- (3) What factors and strategies impact the duration of the recruitment period?

#### 2.1.2. Resource assessment: baseline assessment

- (4) What is the proportion of time spent actively collecting data versus 'inactive' time at study sites?
- (5) What factors and strategies impact the duration of the assessment period?

#### 2.1.3. Process assessment: intervention adherence

- (6) To what extent does the number of intervention sessions provided deviate from the study protocol?
- (7) What is the mean attendance rate of intervention sessions attended by participants?
- (8) What are the most predominant reasons for non-attendance and how much does this vary at different RACFs?
- (9) What factors and strategies increase attendance?

### 2.2. Study overview

The MIDDEL cluster randomised controlled trial aims to determine the effectiveness of small group music therapy (GMT), recreational choir singing (RCS), and their combination on levels of depression in RACF residents: a) aged 65 years or older, b) with a clinical diagnosis of dementia according to ICD-10 research criteria, and c) at least mild

**Table 1**  
Summary of Australia MIDDEL study design.

Study Element	Description
<i>Study Design</i>	Cluster randomised controlled trial; block randomisation (block size = 4 clusters). Six cycles consisting of four clusters in each cycle, total 24 clusters randomised.
<i>Sample Size</i>	Target N = 500 across 8 cycles (32 clusters), actual N = 397 across 6 cycles (24 clusters) (study halted due to COVID-19)
<i>Setting</i>	24 clusters (care home units) within 12 RACFs (2 clusters per RACF) <sup>a</sup> ranging from (9–21 participating residents)
<i>Intervention 1 (GMT)</i>	Small groups (5–10 participants) who received 2 x weekly 45-min group music therapy sessions for 3 months and then 1 x weekly session for a further 3 months. Person-centred, focusing on emotion regulation, identity, processing of life experiences. Delivered by a credentialed music therapist, designed as closed groups.
<i>Intervention 2 (RCS)</i>	Large groups (20 or more participants) who received 2 x weekly 45-min recreational singing sessions (45 min) for 3-months and then 1 weekly session for a further 3-months. Focused on learning and memorising music, social act of singing together. Delivered by a community musician. Note the groups were open so others not enrolled in the study could attend these sessions
<i>Intervention 3 (RCS + GMT)</i>	2 x weekly 45-min sessions of GMT + 2 x 45-min sessions of RCS for first 3 months, then 1 x weekly session of each MI for second 3 months.
<i>Control</i>	Received standard care
<i>Outcome Data Collection</i>	1. Montgomery-Asberg Depression Rating Scale (primary) 2. Clinical Dementia Rating Scale (dementia severity) 3. Neuropsychiatric Inventory Questionnaire (neuropsychiatric symptoms) 4. EuroQoL (EQ-5D-5L) (Generic quality of life) 5. Quality of Life in Alzheimer's Dementia (QoL-AD) 6. Mini Mental State Examination (MMSE) 7. Client Socio-Demographic and Service Receipt Inventory (psychotropic drug use and costs of healthcare) 8. Adverse events 9. Professional Care Team Burden Scale (care staff burden) 10. Days of sick leave of care staff

<sup>a</sup> Cluster is defined as a care home unit with at least 10 eligible and consenting residents. There were two clusters within each RACF in our study and four clusters (across two RACFs) in each cycle.

depressive symptoms, as indicated by Montgomery-Åsberg Depression Rating Scale (MADRS) score of at least 8. GMT is delivered by a trained music therapist with specific focus on affect regulation and attunement to meet psychosocial needs through active, reciprocal music making. RCS is facilitated by a community musician with focus on singing familiar songs. The intervention is delivered twice weekly for 3 months and then once weekly for 3 months, and data are compared between baseline, 3-month, 6-month and 12-month timepoints (see Table 1, Overview of study elements).

### 2.3. Procedure

#### 2.3.1. Recruitment and consent processes

All potentially eligible participants were screened by reviewing RACF resident databases. Participants were then randomly selected from the list and the research team contacted residents and NOK to introduce the study. If the NOK gave verbal consent or expressed interest in the project, a plain language statement and consent forms were sent. Once verbal consent was received by both the resident and NOK, residents could be enrolled in the study. NOK were contacted up to five times after giving verbal consent to encourage the return of signed formal consent forms. The recruiter typically allowed 14 days for the form to be returned before recontacting them. Correspondence with NOK took place by phone, email, post and/or SMS, depending on the NOK's preference.

Recruitment strategies changed across cycles as we gained experience with the recruitment process. Initially, recruitment was spread across seven team members and NOK were asked to collect plain

**Table 2**  
MIDDEL – Recruitment and assessment by cycle.

Cycle (randomised, MM/YY)>	1 (07/18)	2 (10/18)	3 (02/19)	4 (07/19)	5 (11/19)	6 (-)	Total
<b>Residents</b>							
Completed Baseline Assessment	82	71	68	58	71	86	436
Eligible (MADRS $\geq$ 8) and enrolled	76	63	65	47	65	0 (82 eligible)	316 (397 eligible)>
Completed Follow-up 3 months	70	46	55	37	Postponed <sup>a</sup>	-	208 (+65 pending)
Completed Follow-up 6 months	65	43	45	35	Postponed <sup>a</sup>	-	188 (+65 pending)
Completed Follow-up 12 months	58	37	Postponed <sup>a</sup>	Planned	Planned	-	95 (+100 pending)
<b>Staff members</b>							
<b>Recruited</b>							
Completed Baseline Assessment	41	41	15	19	15	-	131
Completed Follow-up 3 months	32	25	9	6	Postponed <sup>a</sup>	-	72 (+14 pending)
Completed Follow-up 6 months	31	15	9	3	Postponed <sup>a</sup>	-	58 (+14 pending)
Completed Follow-up 12 months	25	11	Postponed <sup>a</sup>	Planned	Planned	-	36 (+26 pending)

Note. Each cycle consisted of four clusters (care home units) that were enrolled and randomised simultaneously. MADRS - Montgomery-Åsberg Depression Rating Scale.

<sup>a</sup> Postponed due to lockdown and planned to be conducted after re-opening.

language statements from, and return signed consent forms to, the RACF reception area. This approach was later replaced by one or two team members making direct contact with NOK. We adapted the recruitment manual and added checklists to record the initial date of all contact, mode of contact, actions completed, information provided by NOK, and follow-up required. To reduce the number of days needed to receive signed consent forms, for clusters 9 to 24, NOK were provided with return-addressed postage paid envelopes and asked to return consent forms directly to the research team via email or post rather than leave them at reception of the RACF.

### 2.3.2. Baseline and follow-up assessments

Data to be collected came from multiple sources: a) care staff, b) residents, c) resident medical files, and d) RACF finance officers. Most data could only be collected onsite, but in some RACFs, data could be obtained remotely from an electronic database. We averaged the time taken to actively collect data per resident to be between 110 min and 155 min per assessment period. Active data collection refers to the time the research team were actually engaged in face-to-face assessments, scoring of assessment measures, collecting data from resident files, and entering data into the clinical trial database.

### 2.3.3. Intervention adherence

A number of intervention adherence strategies were developed both prior to and during the study in an attempt to maximise attendance of music intervention sessions. First, we identified an RACF staff member to take on the role of research site coordinator. The research site coordinator was the linking person between the research team and RACF staff and supported the project by assisting in the delivery of interventions and reminding staff and residents of session times.

The research team and RACF management discussed the days and times that were best for scheduling music interventions. Once session times were organised, a weekly schedule was created by the research team and distributed to RACF staff. This schedule was updated and redistributed when sessions reduced in frequency from twice to once per week. The interventions were also often added to the RACFs' own events calendars, which were distributed to residents and families.

Guidelines were developed for intervention facilitators to ensure maximum session attendance, including early arrival at the RACF to prompt staff to prioritise care activities of the study participants and assist them to sessions. However, facilitators also often took more active roles in visiting participants in their rooms or locating them in other parts of the facility, inviting them to the sessions and, where appropriate, assisting them to the session location.

## 2.4. Data collection and analysis plan

Data were captured from May 23, 2018 to March 16th, 2020 (trial

suspended due to COVID-19 outbreak). At that time, we had assessed 436 residents, 397 met inclusion criteria, and 316 were enrolled in the study. Two hundred and sixty-five residents completed some or all of the interventions, 95 were enrolled for the full study period (clusters 1–8) and 190 had completed the 6-month data collection (Table 2). During the initial cycle (clusters 1–4), we conceptualised what resource use we were interested in mapping, developed our research questions, and developed our data collection tools. Therefore, not all data is available for cycle 1. As cycle 6 was halted due to the shutdown of RACFs during COVID-19, we will only report recruitment data for this cycle.

### 2.4.1. Recruitment and consent data

Spreadsheets were developed to capture all data points in the recruitment process: a) the number of attempts to call NOK by phone; b) number of days between initial contact and obtaining verbal consent; c) number of days between initial contact and obtaining formal written consent. Means and standard deviations were used to represent the data across the different care homes.

### 2.4.2. Baseline assessment

Spreadsheets were developed to capture time spent at each site (in hours). Data were categorised into the duration of time spent actively collecting data from a) RACF staff, b) residents, c) hard copies of resident medical records, and d) electronic copies of resident files. We kept records of adverse or unexpected events that negatively impacted active data collection, as well as strategies put in place during different cycles to expedite the process. Means and standard deviations were used to represent the durations of time used for each activity across the different RACFs.

### 2.4.3. Intervention adherence

We aimed to provide 39 sessions of either GMT or RCS (with a minimum of 34), and 78 sessions (minimum of 68) for the cluster randomised to both GMT and RCS. Attendance records were kept for every session, including reasons for non-attendance. We calculated an average attendance rate per RACF by dividing the number of residents who attended each session with the number of residents expected to attend each session, then averaged the percentage attendance across all sessions for each intervention group within each RACF. The data therefore takes into account those participants who were deceased, had withdrawn, or were discharged during the study period. The research team kept notes about the factors impacting the recruitment, assessment, and intervention adherence.

**Table 3**  
MIDDEL – Australian participant’s characteristics at baseline.

	Residents	Staff Members
Assessed at Baseline, n	316	131
Age <sup>b</sup>	86.5 (7.2)	43.7 (11.8)
Female <sup>a</sup>	213 (68.3)	108 (82.4)
English as first language <sup>a</sup>	224 (75.9)	
Other language (but having good knowledge of English)	45 (15.3)	
Other language (and having poor or no knowledge of English)	26 (8.8)	
Country of birth <sup>a</sup>		
Australia	183 (58.7)	
UK	32 (10.3)	
European countries	68 (21.8)	
Other countries	29 (9.3)	
Severity of Dementia <sup>a</sup>		
CDR 0.5 (very mild dementia)	17 (5.5)	
CDR 1 (mild dementia)	46 (14.8)	
CDR 2 (moderate dementia)	109 (35.2)	
CDR 3 (severe dementia)	138 (44.5)	
MMSE <sup>b</sup>	8.0 (7.7)	
MADRS Scale <sup>b</sup>	18.4 (7.6)	
NPI-Q – Severity <sup>b</sup>	10.9 (6.8)	
NPI-Q Distress <sup>b</sup>	12.2 (11.0)	
Staff category <sup>a</sup>		
Registered nurses		6 (4.5%)
Enrolled nurses		3 (2.3%)
Personal care attendants		114 (87.0%)
Leisure staff		8 (6.1%)
Work Experience (years) <sup>b</sup>		8 (4.9)

Notes.  
<sup>a</sup> n (%).  
<sup>b</sup> Mean (SD).

### 3. Results

#### 3.1. Participants

Table 3 reports the participant characteristics at baseline for both care home residents and staff. The mean age of the 316 residents living with dementia who completed baseline assessment was 86.5 years (SD 7.2), 213 (68%) were female, 71 (24%) did not have English as a first language and 129 (41%) percent were born overseas. Results of the Clinical Dementia Rating Scale indicate that 138 (44%) of the sample had a score indicating severe dementia, and 109 (35%) with a moderate level of dementia. The Mini Mental State Examination had a mean score of 8.0 (SD 7.7), the Neuropsychiatric Inventory Questionnaire Severity a score of 10.9 (SD 6.8) and the Montgomery Asberg Depression Scale a

score of 18.4 (SD 7.6). The 131 staff members assessed at baseline were, on average, 43.7 years old (SD 11.8), 108 (82%) were female, 114 (87%) were personal care assistants, with 8 years of experience (SD 4.9).

Data in Table 4 reports the number of attempts made to contact participants’ NOK, the number of days until obtaining verbal consent, and the number of days until formal written consent was received. Data indicate that the resources needed to make contact, obtain verbal consent, and receive formal consent varied substantially across the RACFs.

We found a number of factors increased the duration of the recruitment phase. These included when the participant and/or NOK did not have English as their primary language, and NOKs’ perception of burden on residents, concerns over privacy, and beliefs around what residents could contribute to research. Other factors related to the way the researchers approached the NOK. All identified factors and our data-informed recommendations are reported in Table 5.

#### 3.2. Baseline assessment

Table 6 reports the hours the research team were present on site to collect data from various sources at baseline. The duration of time per resident (total time divided by number of residents recruited) was calculated per home. Data show that the duration of inactive time (time spent waiting to collect data) varied from 28% to 65% of the total time on site. Inactive times were reduced when the research team funded an additional RACF staff member to support resident care on the days the team were on site to collect data.

Data on the frequency and number of days RACFs went into lockdown because of infectious outbreaks are depicted in Fig. 1. While these did not directly impact the resource use, it impacted whether our study could adhere to the study protocol of completing data collection and interventions according to the proposed schedule. Durations of lockdowns during the intervention period ranged from 28 to 72 days of the total 182-day intervention period (6-months). Baseline and follow-up data assessments were impacted by lockdowns ranging from 5 to 28 days. Factors and strategies other than funding backfill staff are outlined in the discussion.

#### 3.3. Intervention adherence

In cycles 1 to 3, the number of intervention sessions provided across each cycle and RACF were relatively consistent ranging from 34 sessions (88% of the planned maximum number of sessions) to 40 sessions (103%) (Table 7). However, of the total number of sessions delivered in the RACFs, the average attendance rates were less consistent, ranging from 63% to as high as 95%.

The number of lockdowns (Fig. 1) affected intervention delivery and total sessions available for attendance, thereby impacting the potential

**Table 4**  
Resources used for recruitment and consent processes.

Cycle	1 <sup>a</sup>		2		3		4		5		6**		TOTAL
	1	2	3	4	5	6	7	8	9	10	11	12	
N residents screened	79	61	60	64	53	45	49	54	43	54	44	60	666
N residents enrolled	40	36	29	34	34	31	21	26	28	37	**	**	316
Mean (SD) attempts for initial contact	No data		1.52 (0.86)	1.89 (1.17)	1.42 (0.70)	1.5 (1.22)	1.38 (0.89)	1.61 (0.84)	2.50 (1.77)	2.10 (1.57)	1.38 (0.71)	1.40 (0.68)	1.67 (1.14)
Mean (SD) No. days between initial contact & verbal consent			0.37 (1.61)	4.64 (12.83)	1.13 (3.29)	2.74 (5.66)	0.21 (0.92)	0.56 (2.80)	1.41 (5.53)	0.24 (0.93)	0.10 (0.55)	0.45 (1.50)	1.17 (4.98)
Mean (SD) No. days between initial contact & decision to decline			23.85 (41.33)	13.69 (28.56)	3.25 (4.13)	26.18 (55.65)	22.00 (33.92)	17.67 (27.50)	5.25 (5.95)	9.82 (14.07)	0.40 (0.55)	3.63 (5.91)	12.31 (29.53)
Mean (SD) No. of days between initial contact & formal consent			60.64 (53.39)	51.88 (62.22)	63.25 (51.54)	18.55 (38.32)	72.00 (34.06)	48.50 (52.27)	57.25 (36.51)	34.36 (30.24)	4.00 (3.74)	11.40 (6.77)	45.92 (46.79)

Recruitment incomplete due to COVID-19.

<sup>a</sup> Data not collected.

**Table 5**  
Factors impacting the recruitment process.

Factor	Description	Recommendations and Considerations
<b>Access to information in first language.</b>	Researchers did not have access to a translator and relied on family members or staff to assist in translating the plain language statements and consent forms to residents and guardians/next of kin for whom English was not a first language	Researchers build in adequate budget to hire professional translators to assist in explaining the purpose of the project and obtaining consent
<b>Administrative burden on guardians/next of kin</b>	Despite the required content mandated by the Ethics committee, feedback from some guardians/next of kin were that consent forms and Plain Language Statement were confusing and time-consuming and subsequently took longer to process and agree to the terms in the consent form or declined to give consent to participate	Plain Language Statements and Consent forms should be simpler than often proposed by Ethics committees and researchers should be encouraged to defend any critique of ethics committees stating that complexity and length of forms is a deterrent to participation. Provide multiple options to communicate with guardians/next of kin - telephone and voicemail, SMS (including texting photographs of signed consent forms), Email and Post (including return-addressed postage-paid envelopes).
<b>Concerns or privacy</b>	Guardians/next of kin commonly cited privacy concerns as a reason for declining, with reference to accessing medical records and medication use	Where medical data is critical to the trial, explain medical data collection after family indicates interest. Where medical data is not essential to understand the research outcomes, omit the collection of this data from the study protocol. Alternatively allow participation into the study even when consent to access medical records is not given.
<b>Concerns over burden on resident, possible risks to resident, and resident's capacity to contribute.</b>	Guardians/next of kin commonly cited concerns about their loved one as a reason for declining, particularly fear of forcing resident to do something undesirable, asking 'too much' of resident, or belief that resident would not be able to make a valuable contribution to study.	In the initial script, emphasise the accessibility of music therapy to residents in late stages of care, and that pre-existing musical skills are not expected. Emphasise role of control group and data collection in running a quality study Reassure that the project is voluntary and residents can withdraw anytime
<b>Beliefs around needs of people with dementia and/or depression.</b>	Guardians/next of kin commonly cited concerns that the study would be contraindicated to the needs of the resident as a reason for declining. Guardians/next of kin frequently stated they felt it was preferable to not disturb resident, make demands of them,	Emphasise team's expertise in aged care and carefully monitoring agitation, depression and other psycho-emotional concerns.

**Table 5 (continued)**

Factor	Description	Recommendations and Considerations
<b>Communication from RACF to families about project prior to recruitment calling.</b>	Care home staff did not always disseminate the information about the study to next of kin. Therefore guardians/next of kin could be suspicious and dismissive when telephoned by researcher if they had no prior knowledge of the project.	Post a "postcard" of the research project at least one week prior to making a phone call to ensure the next of kin is aware of the study. Phone manner impacts openness to participate. Sound cheerful, professional, knowledgeable but not overly formal. To maximise success, a recommended recruitment script guiding initial contact would spend 10 s stating that you are music therapist first, researcher second, link your connection to the residential care home, a care home staff name, and the resident's name. Practice therapeutic listening skills to build rapport and establish commitment with families. Many families share stories of strengths, concerns, and grief about their family member's (the resident) ongoing loss of functioning

for participants at some RACFs to reach intervention adherence. Even when COVID-19 was excluded from the data, only one RACF in cycles 1 to 4 had less than 21 days of lockdown. Three RACFs had a total of 35 or more days of lockdown (approximately 20% of the intervention period). As can be seen in [Table 7](#), to reach the minimum number of sessions for adherence, the majority of RACFs required longer than the 26-week intervention period defined in the protocol.

We recorded reasons for individual participant non-attendance and were able to identify those that were the most common. Non-attendance was organised into four broad categories:

- (10) Resident declined (resident declined attending on the day or walked out prior to session starting);
- (11) Health reasons (resident unwell, in hospital, bedbound or did not attend due to behavioural or psychological symptoms of dementia);
- (12) Resident not available (due to staff resources: not ready in time for sessions, personal care, health care, or as they were otherwise occupied: out of RACF, with visitors); and
- (13) Not known (when reasons for non-attendance were not known).

The frequency of reasons for non-attendance per category are reported in [Table 7](#) (please see supplementary material for all reasons for non-attendance within each category). At RACF 1 (cycle 1), 75% of non-attendance was due to participants declining, whereas only 15% did not attend because of health reasons. This contrasts with RACF 7 (cycle 4), where residents declining attendance was low and non-attendance due to health reasons was high. Non-attendance due to the resident not being available also fluctuated between RACFs, from only 8% and 13% at RACFs 1 and 2 (cycle 1), to 30% at RACF 4 (cycle 2), and 32% at RACF 7 (cycle 4). It should be noted that the higher number of unknown reasons in cycle 5 is due to the recruitment and employment of two new

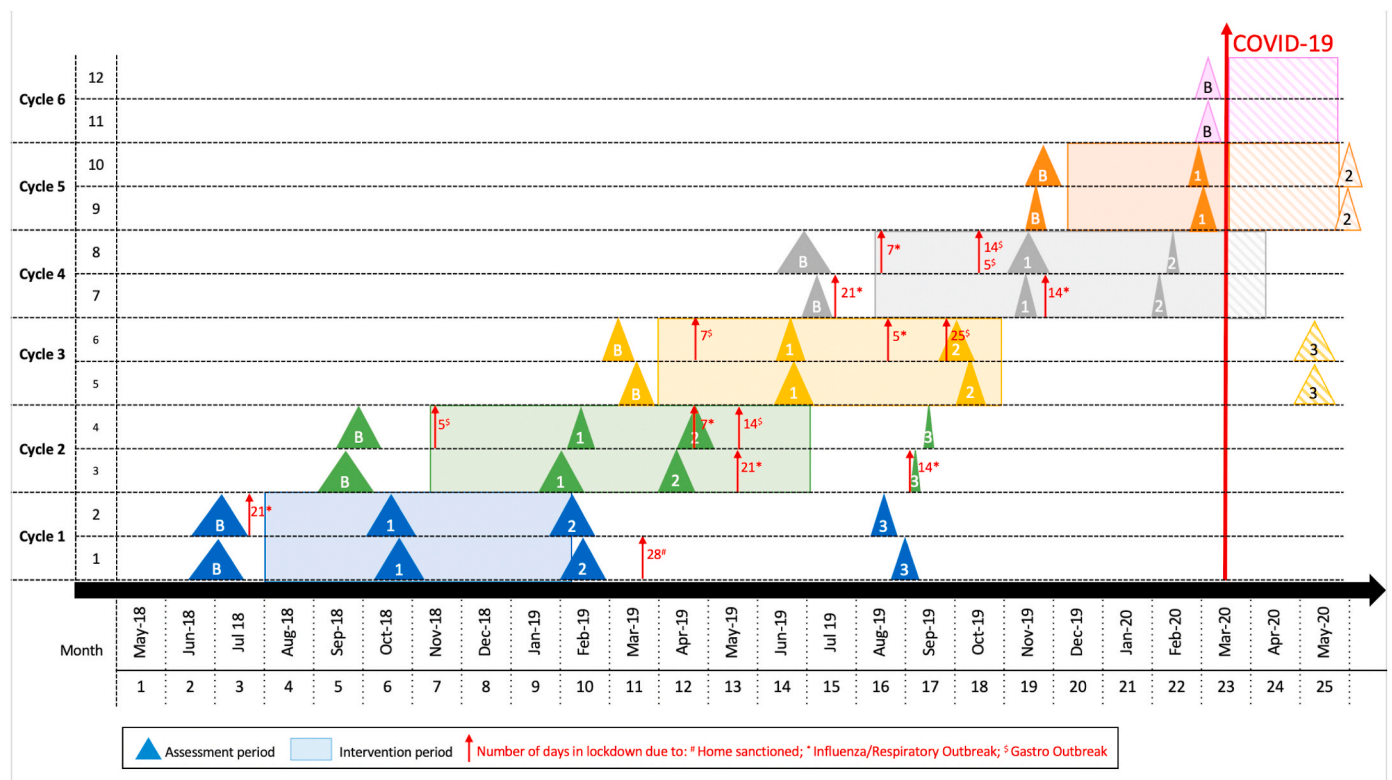
**Table 6**  
Resources used for completion of baseline assessments.

Cycle	1	2	3	4	5	6	7	8	9	10
RACF <sup>a</sup>	1	2	3	4	5	6	7	8	9	10
Total residents completed baseline assessment	44	38	31	40	35	33	26	32	34	37
Total enrolled	40	36	29	34	34	31	21	26	28	37
Demographic (hours)	7.3	6.3	5.2	6.7	5.8	5.5	4.3	5.3	5.7	6
Contact with resident (hours)	22	19	15.5	20	17.5	16.5	13	16	17	18
Contact with RACF staff (hours)	18.3	15.8	12.9	16.7	14.6	13.8	10.8	13.3	14.2	15
Waiting for resident or care staff (hours)	72.6	60.9	62.4	58.6	34.1	18.2	13.9	13.4	35.1	39
Proportion of waiting time(%)	60.5	59.7	65	57.5	47.4	33.7	33.1	27.9	48.8	50
Duration per resident enrolled (hours) <sup>b</sup>	3	2.8	3.3	3	2.1	1.7	2	1.8	2.6	2.1
Backfill (hours) <sup>c</sup>	0	0	0	0	12	6	0	6	12	0

<sup>a</sup>One RACF contain two clusters.

<sup>b</sup>Calculation based on total time on the floor divided by the total number enrolled, duration per resident includes assessment and waiting time.

<sup>c</sup>Backfill indicates the number of hours the research team funded an additional RACF staff member to assist us in collecting data from the clusters rather than just relying on staff already rostered to work on the days the research team were on site.



**Fig. 1.** Lockdowns by cycle across the trial.

interventionists who did not always record reasons for non-attendance. Factors and strategies that increase participant attendance rates are outlined and discussed in the discussion section.

#### 4. Discussion

##### 4.1. Resources use during recruitment

Our data indicate that the resources required to recruit a participant into the study is considerable, even with a readily available potential pool of participants. Researchers planning a study need to be aware that there may be a significant time lag between initial verbal consent and receiving the signed consent form. Delays in beginning the baseline assessments and intervention delivery due to waiting to obtain signed consent can be costly to any trial. To reduce the burden on NOK and to expedite the formal consent process, we recommend providing a short and simple plain language statement and consent form that can be

signed and emailed or sent as a text message so the resident could be enrolled in the trial well before arrival of the signed hard copy.

We also found that, despite the enthusiasm of researchers and communication of potential benefits for residents, NOK often held concerns that their family member would be overly burdened, the research would be contraindicated to resident needs, and/or that their privacy would be at risk. It was important to outline the link to RACF staff who had passed on the NOK's details, and establish the NOK's interest in the trial early on. We also highlighted the research team's expertise and explained who would have access to residents' information and how it would be protected when describing what consent entailed and the need to collect medical information.

Another challenging aspect of recruitment was the inconsistency of RACFs in communicating with families about the project. In some cases, RACFs informed families of the upcoming study in advance through family information sessions or weekly newsletters, but this was not carried out uniformly across the RACFs. Where communication was

**Table 7**  
Intervention adherence across facilities.

Cycle	1	2	3	4 <sup>a</sup>	5 <sup>a</sup>	6	7	8	9	10	
<b>RACF</b>	1	2	3	4	5	6	7	8	9	10	
<b>Mean duration of MI in wks (% wks in protocol)</b>	26 (100)	27 (104)	31 (119)	31 (119)	30 (115)	31 (119)	29 (112)	30 (115)	12 (46)	9 (35)	
<b>Mean sessions per grp (% sessions in protocol)</b>	40 (103)	38 (97)	38 (97)	38 (98)	38 (97)	34 (88)	35 (90)	32 (82)	17 (44)	19 (49)	
<b>Mean attendance rate per session</b>	63%	95%	86%	71%	65%	68%	71%	60%	68%	76%	
<b>Total sessions missed and reasons for non-attendance</b>	<b>Total N (%)</b>	271 (37)	110 (6)	50 (14)	469 (32)	321 (29)	277 (29)	73 (29)	432 (42)	179 (32)	85 (25)
	<b>Declined N (%)</b>	203 (75)	52 (47)	11 (22)	257 (55)	152 (47)	160 (58)	7 (10)	294 (68)	39 (22)	42 (49)
	<b>Health N (%)</b>	41 (15)	39 (35)	27 (54)	50 (11)	92 (29)	45 (16)	43 (59)	47 (11)	53 (29)	16 (19)
	<b>Not Available N (%)</b>	22 (8)	14 (13)	12 (24)	141 (30)	60 (19)	50 (18)	23 (32)	67 (16)	45 (25)	18 (21)
	<b>Not Known N (%)</b>	5 (2)	5 (5)	0 (0)	21 (4)	17 (5)	22 (8)	0 (0)	24 (6)	42 (23)	9 (11)

Note. MI: Music Intervention. Number of sessions/weeks in protocol = 39 sessions over 26 weeks. Mean sessions per group (M sessions provided across all MI group/s for each RACF); Mean attendance rate per session (# residents attended/# residents expected to attend); Percentage of total sessions missed (# sessions missed/# residents expected to attend across all sessions delivered); Percentage reasons for non-attendance (# sessions missed for that reason/total # sessions missed).

<sup>a</sup> Music Interventions incomplete due to COVID-19.

limited, a number of family members did not appreciate being cold-called or they simply just ended the call before our team could explain its purpose. We suggest that sending a postcard advertising the study a week prior to contacting the NOK as an advanced notification may minimise the premature termination of calls.

#### 4.2. Resources used during baseline and follow-up

Prior to commencing the trial, we had piloted the duration of time needed to actively collect data for each participant. However, we did not anticipate the substantial duration of on-site waiting time needed, an issue identified by previous authors [2,3]. We had factored two weeks to collect baseline data for each cycle. However, as our data indicated, the amount of wait time was almost double the amount of time spent actually engaged in collecting data, thereby extending the baseline data collection period beyond our planned study timeline. Researchers need to consider that for every hour spent with a resident, there will be another 2 h of time spent waiting to access residents or staff. To our knowledge, this is the first study to quantify the ratio of active and inactive time spent on site to collect data in RACFs.

We engaged a number of strategies to increase efficiency and reduce number of days involved in data collection. As is common knowledge, staff are under pressure to provide high quality care often under difficult conditions due to staff shortages, heavy work schedules, time constraints and demands of the caring role. We were sensitive to this issue and checked in regularly with staff during the day, accompanying them during tasks, such as walking between residents' rooms, writing notes, and sitting with residents, so that data collection could commence as soon as possible. We tried wherever possible to minimise impact on staffs' daily tasks and respected their wishes to have scheduled breaks as a break from all work. When staff were able to give us their time, we persistently showed our appreciation for committing to the project. We noted that providing space for staff to vent and discuss a range of issues also increased staff commitment to provide well considered responses.

Another strategy that assisted in reducing the amount of waiting time was identifying and avoiding conducting assessments at "low resource" times of the day or days of the week. For example, we avoided approaching staff on days where there were a lot of casual staff rostered on, or during the morning care routine where staff were engaged in assisting residents to get ready for the day. However, the most effective strategy we employed, which was not commenced until cycle 3, was to fund backfill staff. An additional staff member on the floor ensured that a) participants were prioritised and ready for our assessments and b) that a staff member would be available and "off the floor" to assist us to

complete data collection. As evidenced in our data, this significantly reduced the wait time during cycles 3, 4, and 5.

#### 4.3. Assessment of intervention adherence

Adherence was impacted at the organisational and individual participant level. Organisational impacts included the series of lengthy lockdowns (in addition to the unprecedented impact of COVID-19), meaning facilitators were unable to deliver interventions as planned. As lockdowns were more prevalent in winter months, researchers could consider scheduling intervention periods in summer to minimise the frequency and length of lockdowns. Further, given the significant disruption lockdowns can be to a clinical trial, future researchers might consider incorporating a remote/telehealth delivery mode into the protocol for action during lockdown periods.

Differences in staff resources and commitment led some RACFs to have lower attendance rates than others. The number of staff rostered on and their workloads, as well as staff attitudes, knowledge of, and commitment to the research, can influence whether they are able or motivated to prioritise residents' attendance of interventions. This includes prioritising the completion of participants' care routines and assisting residents to the session location in time for scheduled sessions. It is important to recognise and acknowledge that RACFs are often understaffed and the requirements of clinical research may be felt as another demand on staff. The interventionists implemented a number of strategies in an effort to establish, maintain or increase attendance rates. These included establishing positive relationships and open communication with staff and taking an active role in visiting residents in their rooms, and inviting and assisting them to sessions. Interventionists also developed relationships with regular visitors of residents who would often attend sessions and therefore encourage participant attendance.

#### 4.4. Limitations of research

While the learnings captured here provide useful insights into the resources needed in RACF trials, keeping a record of the amount of time devoted to the different activities associated with a study is, in itself, a resource intensive and quite a rudimentary means of measuring resource use. While we captured the mean number of phone calls required to NOK to recruit a participant, we did not capture the time spent on the phone talking through the study, and how varied that duration might be depending on the type of relationship the NOK had with the participant. Further, we did not attempt to calculate the cost of recruitment or assessment. Future studies would benefit from examining more closely

the cost-savings of providing backfill to staff.

## 5. Conclusion

Our data show that the resources needed to recruit, assess and deliver interventions encompass significant amounts of time of inactivity. Most notably, the amount of waiting time for undertaking assessments within RACFs is approximately double the actual research activity itself. Research timelines need to accommodate the long lead time in recruiting with respect to the delays between verbal and written consent. This has significant impact on those trying to deliver group psychosocial interventions. Being respectful of staff time and providing additional backfill will lead to more positive interactions between research and RACF staff, which may in turn expedite assessment duration. Further, our experiences indicate that buy-in at multiple levels, from key members of management to care staff, families and residents themselves, is important to ensure more residents are attending sessions as scheduled.

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## Appendix A. Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.conctc.2020.100675>.

## Disclosure of interest

The authors declare that they have no conflict of interest.

## Authors' contributions

FB, YEL, PSS, TS designed the process and resource feasibility study and analysed the data. CG designed the overarching MIDDEL study. YEL, PSS, AC, and IC collected data. All authors contributed to the drafting of the manuscript.

## Data availability statement

The data used and analysed in this manuscript was collected alongside an ongoing trial and therefore the data is presented as pooled data rather than by study arm. The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request and a full data set will be available on completion of the full trial.

## Ethics approval and consent to participate

Ethical approval has been obtained from the Medicine and Dentistry Human Ethics Sub-Committee at the University of Melbourne, Australia (approval date: January 12, 2018, Ethics ID 1750400). Participants all provided informed written consent or assent from proxy where relevant to participate in the study.

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