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Remini-Sing RCT: Therapeutic Choir Participation for Community-Dwelling People with Dementia and Their Primary Caregivers

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Abstract

*Dementia negatively affects the wellbeing of both caregivers and care recipients. Community-based therapeutic choir singing offers opportunities for music participation and social engagement that are accessible and mutually enjoyable for people with dementia and their family caregivers and promotes shared and meaningful musical interactions, which may support relationship quality. This study aimed to investigate the impact of the Remini-Sing therapeutic choir intervention on relationship quality, quality of life, depression, and social connectedness for dyads, as well as caregiver burden and care recipient anxiety. A randomized-controlled trial design was used with a target sample of 180 dyads. Due to recruitment difficulties, 34 participant dyads were recruited and randomly assigned to a 20-week group singing condition (*n = 16*) or a waitlisted control group (*n = 18*). Participant dyads consisted of people with dementia and their family caregivers who resided at home in the community. The Remini-Sing therapeutic choirs were held in community settings. Assessments were conducted by masked assessors at baseline, 11 weeks, and 21 weeks. Twenty-one dyads completed assessments at the primary timepoint (Week 11). Issues with recruitment and retention resulted in an unpowered study with no statistically significant findings. Mean decreases in anxiety and depression for choir participants with dementia were supported by medium to large effect sizes, indicating a potential intervention effect to be explored in future powered studies. Key learnings related to study design are discussed regarding recruitment, retention, participant burden, and sustainability, with recommendations made for future dementia research.*

Keywords: dementia, community, singing, music therapy, choir, caregivers, randomized-controlled trial

Introduction

Dementia is an umbrella term for degenerative neurological conditions that affect a range of cortical functions, including memory, comprehension, orientation, communication, and behavior (World Health Organization, 2019). Dementia can have a significant impact on health and quality of life, both for those with a diagnosis and for those who support them with informal care (O'Rourke et al., 2015; Smith et al., 2022). With the prevalence of dementia growing exponentially worldwide, the World Health

Organization has identified supporting people with dementia as a public health priority (World Health Organization, 2017). In Australia, it is estimated that over 470,000 people are living with dementia, approximately 76% of whom live in the community, and are typically supported by an informal primary caregiver, usually a spouse/partner (42%) or offspring (44%) (AIWH, 2021). Family members often provide over 40 hours of "informal" care per week (Brooks et al., 2015).

Supporting People with Dementia to Live at Home

A strategic priority of the Australian government is to support people with dementia to live for as long as possible in the home of their choice (AIWH, 2021) and this is also part of the World Health Organization's Global Action Plan (World Health Organization, 2017). The family home, with familiar people, objects, and memories, provides optimal environmental and care conditions for people living with dementia (Alzheimer's Australia, 2013), higher quality of life and health outcomes (Olsen et al., 2016), and is often preferred by people living with dementia (Cunningham et al., 2020). Supporting people with dementia to remain in the family home also reduces financial costs for individuals and society (AIWH, 2021). However, supporting a family member with dementia to live at home can be challenging, and providing ongoing care can have a negative impact on a caregiver's physical and psychological wellbeing (O'Rourke et al., 2015). Some aspects of dementia have been found to correlate with reduced health and wellbeing outcomes for caregivers, such as neuropsychiatric symptoms or changes (including anxiety, agitation, depression, and/or hallucinations), or increased reliance on support for activities of daily living (Lethin et al., 2017). However, other factors, such as social isolation due to stigma, financial challenges, pre-existing health backgrounds, and availability of other support systems may also impact caregiver wellbeing (McGillick & Murphy-White, 2016). Positive aspects of caregiving, such as mutuality in relationship, sense of achievement, and family cohesion have been noted as positive aspects of caregiving that can support the wellbeing of caregivers (Yu et al., 2018). Relationship quality is recognized as a major factor that influences the health and wellbeing of both the person with a diagnosis and their caregiver and consequently impacts their ability to live together in the family home (Yu et al., 2018). Similarly, practical support (such as training or education) and psychosocial support (such as support groups) for caregivers can also increase their ability to provide informal care and maintain their own wellbeing (Dawson et al., 2015). A need, therefore, exists for activities and resources that can support relationship quality, sustain caregivers in their caring roles, and help people living with dementia to remain independent for as long as possible (Yu et al., 2018).

Music Therapy to Support People Living with Dementia and their Caregivers

There is a growing evidence base to suggest that music therapy can support both people with dementia and caregivers to improve and maintain health and wellbeing (Moreno-Morales et al., 2020; Särkämö, 2018; Thompson et al., 2021; Van der Steen et al., 2018). Areas of the brain responsible for processing music are retained until late in the trajectory of dementia, which can aid in compensating for other areas of the brain that are damaged during dementia progression (Brancatisano & Thompson, 2019). Consequently, music can be used therapeutically to support communication, social connection, and stimulate autobiographical memories for people with dementia (Brancatisano & Thompson, 2019). For caregivers, music therapy has been found to assist with building confidence in their caregiving role and development of coping strategies (Baker et al., 2018). Music therapy, and other group music programs, have also been highlighted as an important tool that people with dementia and caregivers can use to maintain relationships and other social connections (Lee et al., 2020; McDermott et al., 2014; Unadkat et al., 2016), and participating in caregiver–recipient dyads has been noted as preferable (Clark et al., 2021). Choir singing has been highlighted as a particularly accessible and enjoyable means of using music to support community-dwelling people with dementia and caregivers (Tamplin et al., 2018; Thompson et al., 2021) and group singing in residential care settings has been shown to significantly reduce depression and dementia symptoms (Baker et al., 2022; Werner et al., 2017). However, there is a lack of rigorous research that investigates the impact of choirs designed and led by credentialed music therapists specifically to address wellbeing outcomes for people living at home with dementia (Thompson et al., 2021). There is also no research published that compares the effects of therapeutic choir participation on relationship quality against a usual care control condition (Thompson et al., 2021).

Background to Current Study

The current study details a pragmatic randomized-control trial (RCT) that built on previous feasibility research investigating the effects of participation in the Remini-Sing therapeutic choir program with 10 community-dwelling people with dementia and their family caregivers (Tamplin et al., 2018). The RCT was pragmatic because it recruited participants living with dementia in the community and was conducted in a real-world setting rather than under optimal or laboratory conditions. The feasibility study emphasized supporting relationships between caregiver–care recipient dyads, as well as providing accessible opportunities for ongoing musical participation, social engagement, and community involvement. Learnings from the feasibility study led to some changes in quantitative measures used within this RCT. For example, the Quality of Carer Patient Relationship (QCPR) scale had not previously been validated for use by people with dementia, and in the feasibility study, we found that this measure was too difficult for participants with a diagnosis to complete (Tamplin et al., 2018). Thus, in the RCT, only caregivers were asked to complete the QCPR. In the feasibility study, we also aimed to focus on the positive aspects of the caregiving role (rather than the caregiver burden) through the Positive Aspects of Caregiving Questionnaire (PACQ), however, some participants reported disliking this measure, which they felt asked them to equate their self-worth with their caregiving role. The more commonly used Zarit Burden Scale was used in the RCT instead, despite acknowledging that the language around "caregiver burden" was problematic (Dementia Australia, 2024). A validated measure of depression for the person with dementia (rather than apathy as assessed in the feasibility study), and a validated standard measure of health-related quality of life for caregivers (rather than life satisfaction and flourishing) were also introduced in the RCT. Finally, we added a measure of social connectedness for both members of the dyad based on the qualitative results of the feasibility study, which suggested that social connection was perceived as an important outcome by participants (Tamplin et al., 2018).

Aims of this Study

The RCT aimed to answer the following research questions: can therapeutic choir participation: (1) improve relationship quality (primary outcome) between community-dwelling people living with dementia and their primary caregivers, (2) improve wellbeing outcomes for caregivers (depression, quality of life, social connectedness, and caregiver burden), and (3) improve wellbeing outcomes for people living with dementia (depression, quality of life, social connectedness, and anxiety). Qualitative data were gathered through participant interviews, in addition to the quantitative measures, to understand how dyads experienced the therapeutic choir participation. An interpretative phenomenological analysis of this qualitative data has been published elsewhere (Thompson et al., 2022).

This study was co-funded by the Australian National Health and Medical Research Council and the Australian Research Council (GNT1106603) and led by researchers at The University of Melbourne in partnership with a community-based aged care service provider (Uniting AgeWell). The study was conducted according to the guidelines of the Declaration of Helsinki, and ethics clearances were provided by The University of Melbourne Human Research Ethics Committee (ID# 1749728) and the Alfred Health Human Research Ethics Committee (ID# 488/18) and written informed consent was obtained from all participants. The study was prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN 12617001513303).

Methods

Study Design

A single-masked parallel-group randomized controlled trial was used to compare groups. Participant dyads including a caregiver (CG) and care recipient (CR) living with dementia were recruited from seven Australian sites: five from metropolitan Melbourne areas, one metropolitan Hobart site and one country Victorian town (Bendigo). The sequentially numbered opaque sealed envelopes (SNOSE) method (Schulz & Grimes, 2002), coordinated by a person independent of the research team, was used to allocate participant dyads to the intervention group or wait-list control group.

The intervention consisted of weekly community-based therapeutic choir sessions co-facilitated by two registered music therapists. Masked assessors administered all outcome measures at baseline (T0), week 11 (T1), and week 21 (T2). For obvious reasons, it was not possible to mask participants or music therapists providing the choir intervention in this trial.

As this was a pragmatic trial and recruitment was much more difficult than anticipated, the research steering committee made a practical decision early in the trial to reduce the primary timepoint for analysis from 21 weeks (T2) to 11 weeks (T1). This decision was made with the aim of maximizing retention, reducing participant burden, and increasing the viability of the choirs with small numbers by allowing control participants to join a choir after their T1 assessment. As we already had planned to conduct assessments at 11 weeks and 21 weeks, this meant that the 21-week assessment now functioned as a follow-up assessment for intervention participants rather than the primary endpoint. A 10-week intervention period is consistent with previous research, which examined the effects of group singing for people with dementia and their caregivers living in the community (Särkämö et al., 2014).

Participants

Based on an assumed medium effect size (0.45) for the primary outcome of CG/CR relationship quality, as measured via the Quality of Caregiver Patient Relationship (QCPR) survey (Spruytte et al., 2002) a sample size of 160 dyads was required to yield a power of 0.8 and reject the null hypothesis at the 0.05 level of significance. Allowing for a 10% drop-out/non-completion rate, we planned to recruit 180 CG/CR dyads. Eligible dyads were identified through healthcare providers, community service providers, and dementia-specific support services. A media campaign was launched to promote study recruitment (generating six radio interviews and two live television interviews) along with paid radio advertisements and social media. Inclusion criteria for care recipients (CR) with dementia included: aged >60 years with a confirmed diagnosis of dementia, OR probable dementia (i.e., a cognitive impairment as indicated during screening via Mini Mental State Exam (MMSE) score < 24 (Folstein et al., 1975), OR features consistent with Alzheimer's type dementia as per DSM-V (American Psychiatric Association, 2013)). Both members of the dyad needed to be living in the community, have functional hearing and speak English. The CG needed to be a spouse, close family member (e.g., adult child), or friend aged at least 18 years.

Measures

The 14-item QCPR scale (Spruytte et al., 2002), a validated measure used to answer the primary research question, focused on relationship quality for the CG/CR dyad. The QCPR was completed by CG participants in our feasibility study (Tamplin et al., 2018) and has been used in other dementia intervention trials with CG/CR dyads (Cove et al., 2014; Subramaniam et al., 2014). Items are scored on a 5-point rating scale, with a total possible score range of 14–70 and higher scores indicating better relationship quality.

A battery of additional validated instruments (see Table 1) was used to answer secondary research questions relating to four aspects of wellbeing for all participants: depression, connectedness, quality of life, and anxiety (CR only) or burden (CG only).

Intervention

The planned intervention included 20 weekly 2-hr therapeutic choir sessions but the primary endpoint was revised so that it was collected after 10 weekly 2-hr sessions. Sessions were co-facilitated by two registered music therapists and included 90 min of warmup singing exercises and singing of preferred and new songs, and 30 min for social interaction. All facilitators completed a 1-day training program to deliver the therapeutic choir intervention according to the research protocol and were provided with an intervention protocol manual and regular supervision. Accompaniment was provided by one of the facilitators via guitar or keyboard. Sessions were structured to include various therapeutic elements (e.g., opportunities for connection and reminiscence, relationship building, wellbeing check-ins, etc.) but were flexible so that the music therapists could adapt the session to meet the needs of the participants. The intervention was designed to support the relationship of the dyad, as well as address the individual needs of each participant from a strengths-based perspective. This model was informed by theories of person-centered care (Kitwood, 1997) and community music therapy (Stige & Aarø, 2011).

Table 1.

Secondary Outcome Measures

Outcome	Measure	Number of items	Interpretation of scores
Person with dementia			
Depression	Cornell Scale for Depression in Dementia (CSDD) (Alexopoulos et al., 1988)	19	Scores range from 0 to 38 with higher scores indicating greater depression and scores below 6 indicating an absence of significant depressive symptoms.
Anxiety	Rating Anxiety in Dementia (RAID) (Shankar et al., 1999)	18	Scores range from 0 to 54 with higher scores indicating greater anxiety and scores above 11 suggesting significant clinical anxiety.
Connectedness	Social Connectedness Scale (SCS) (Lee & Robbins, 1995)	8	Scores range from 8 to 48 with higher scores indicating stronger feelings of connectedness.
Quality of Life	Quality of Life in Alzheimer's disease (QoL-AD) (Logsdon et al., 1999)	13	Scores range from 13 to 52 with higher scores indicating better quality of life.
Caregiver			
Depression	Patient Health Questionnaire (PHQ-9) (Kroenke, et al., 2001)	9	Scores range from 0 to 27 with higher scores indicating greater depression and scores below 9 indicating the absence of depressive disorder.
Burden	Zarit Burden Interview (ZBI) (Bédard et al., 2001)	22	Scores range from 0 to 88, with higher indicating greater burden and scores above 21 indicative of moderate burden of care
Connectedness	Social Connectedness Scale (SCS) (Lee & Robbins, 1995)	8	Scores range from 8 to 48 with higher scores indicating stronger feelings of connectedness.
Quality of Life	Assessment of Quality of Life 8 dimensions (AQoL-8D) (Richardson et al., 2014)	35	Unweighted scores range from 35 to 176 with higher scores indicating worse quality of life.

Participants completed a music preference form prior to commencing and information from this was used to form the initial choir repertoire, but this was added to during sessions as new songs were suggested by participants. Therapists also introduced new songs to teach as rounds or song mash-ups to provide some gentle cognitive challenges. Sessions typically followed the following format: (1) *Warm Up* (10 min)—including vocal warm-ups and gentle exercise to encourage relaxation, movement, and social engagement, (2) *Familiar Song Singing* (70 min)—participants were encouraged to select a song from their song repertoire list or suggest a new song to add to this list, (3) *Simple Part Singing* (10 min)—more complex singing tasks based on the musical preferences of the participants, and (4) *Afternoon Tea* (30 min)—participants were encouraged and supported to connect over refreshments.

Participating dyads allocated to the control group received usual care in the community for the initial 10-week intervention period. This meant that they went about their normal routine and did not participate in a choir or any other dyad-focused intervention. After control participants had completed T1 assessments, they were offered the opportunity to join a therapeutic choir that had been established for the study in their area.

Statistical Analysis

Changes in outcome measures from T0 (baseline) to T1 (Week 11) between groups (intervention vs control) were analyzed via ANCOVA with baseline scores as covariates. Analyses were conducted according to intention-to-treat principles, meaning that all available data were analyzed as allocated. Given the small sample size, no corrections for multiple comparisons were made and the significance level was set at 0.05. Multiple imputation using R (version 3.6.1) and the mice package (version 3.6.0) was used to account for missing data using linear regression and 50 imputed datasets.

For family caregiver data, all variables were included in the imputation model. For the person with dementia data, the multiple imputation failed to converge when all variables were included. To solve this, only variables with a pairwise correlation of at least 0.45 were included in the imputation model. The treatment group was never used to impute missing baseline data. We used Hedges g to calculate effect sizes outside of the ANCOVA model (dividing the difference between the two groups by the pooled standard deviation) using the Cambridge Effect Size Calculator (https://www.cem.org/effect-size-calculator).

Results

With seven recruitment sites, we had planned to establish seven Remini-Sing choir groups with 180 participant dyads (ACTRN 12617001513303). Due to low recruitment numbers, only six choirs were established, and only three choirs had sufficient numbers to continue for the full duration of the study (Figure 1).

Recruitment took place over 3 months and 61 dyads initially consented to be involved in the study. Of these, 27 dyads who initially consented to participate, withdrew prior to group allocation and the commencement of the study. Reasons for withdrawal included illness progression beyond eligibility criteria ($n = 7$), caregiver illness ($n = 4$), and change of mind following initial assessment ($n = 16$).

Randomization processes were adequate with no significant baseline differences between groups (Table 2). The recruited cohort was predominantly white, well-educated, and in a spousal

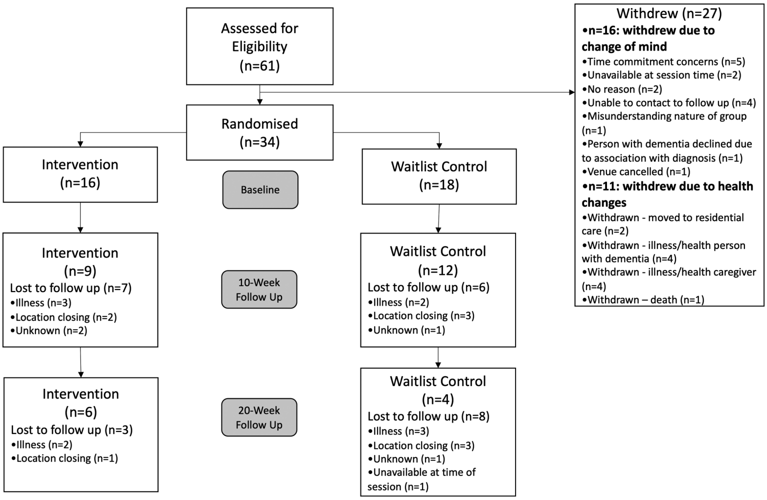

Figure 1.
Consort Flow Chart

Table 2.

Participant Demographic Details

	Control ($n = 18$)		Intervention ($n = 16$)	
	CG	CR	CG	CR
Female (male)	12 (6)	10 (8)	13 (3)	6 (10)
Mean age (range)	70 (51–86)	80 (62–96)	64 (53–82)	77 (72–87)
Aboriginal and Torres Strait Islander	2	0	0	0
English as an additional language	3	4	3	3
Education—completed high school minimum	16[a]	15	12	13
MMSE score (mean/max)	N/A		N/A	17.6/30
CG/CR relationship—parent/child	4		4	
CG/CR relationship—spouse/domestic partner	14		12[b]	

[a] Data missing for 2 CGs.

[b] One CG/CR relationship identified as "Friend".

relationship ($n = 25$). There were also several parent/adult child dyads ($n = 8$).

Twenty-one dyads completed assessments at the primary timepoint (T1–week 11), but only 10 dyads remained in the study and completed the 20-week assessment (T2) (see the Consort Flow Chart in Figure 1). Statistical analysis was, therefore, conducted using baseline and 10-week data only.

No statistically significant differences were found between intervention and control groups in change from baseline (T0) to 10 weeks (T1) on any measure (Table 3, Figure 2).

The primary outcome of relationship quality was high at baseline for both groups, with a mean QCPR score of 60.1 out of a possible 70 for intervention participants and 57.1 for controls. The slight mean decrease in QCPR scores for both groups was not statistically significant with an adjusted difference in means of −1.8 (95% CI −6.4, 2.8, $P = .42$). Many of the secondary outcome measures were high at baseline for both groups and did not change significantly at

TABLE 3.

Outcome Measure Summary Statistics and ANCOVA Results

		Intervention			Control			ANCOVA analyses			
	Measure	T0 mean (SD)	T1 mean (SD)	T1–T0	T0 mean (SD)	T1 mean (SD)	T1–T0	Effect size–hedges *g*	Diff in means[a]	95% CI	*p*-value
CR measures	CSDD_SR	7.4 (5.1)	5.0 (4.8)	−2.4	6.5 (5.1)	8.5 (4.4)	2.0	−0.7	−3.5	−7.7, 0.7	0.09
	RAID_SR	12.7 (6.7)	7.8 (6.0)	−4.9	13.6 (10.7)	13.6 (5.8)	0.1	−0.9	−5.3	−12.0, 1.3	0.11
	SCS_PWD	41.6 (4.0)	42.9 (4.5)	1.3	40.6 (7.9)	42.2 (4.1)	1.6	0.2	0.2	−8.9, 9.4	0.95
	QoLAD_SR	37.0 (2.8)	36.5 (5.9)	−0.5	38.6 (4.7)	38.1 (5.4)	−0.4	−0.3	−0.4	−7.5, 6.8	0.92
	CSDD_PR	5.7 (5.2)	3.8 (4.0)	−1.9	5.9 (3.9)	6.7 (4.5)	0.8	−0.6	−3.0	−7.0, 1.0	0.13
	RAID_PR	8.5 (7.8)	5.7 (5.3)	−2.9	10.6 (6.8)	8.5 (5.5)	−2.1	−0.5	−2.8	−7.8, 2.2	0.25
	QoLAD_PR	32.3 (5.9)	33.5 (9.7)	1.1	31.4 (6.1)	30.1 (6.2)	−1.3	0.4	3.3	−3.6, 10.2	0.32
CG measures	QCPR	60.1 (5.2)	56.8 (8.1)	−3.3	57.1 (8.0)	55.8 (8.0)	−1.3	0.1	−1.8	−6.4, 2.8	0.42
	PHQ9	14.1 (3.3)	14.2 (5.3)	0.1	13.2 (3.9)	13.4 (4.9)	0.2	0.2	−0.1	−3.6, 3.3	0.93
	ZBI	33.4 (11.7)	33.2 (12.2)	−0.2	31.3 (11.0)	32.3 (15.7)	1.1	0.1	−1.1	−10.7, 8.6	0.82
	SCS_CG	39.6 (6.9)	39.3 (9.3)	−0.2	39.9 (7.9)	41.2 (6.1)	1.3	-0.2	−1.6	−6.6, 3.5	0.52
	AQoL_total	73.7 (14.8)	70.4 (16.0)	−3.3	71.1 (16.8)	67.0 (16.7)	−4.1	0.2	0.4	−8.6, 9.4	0.93
	AQoL_psycho social	52.3 (11.9)	49.1 (13.4)	−3.2	49.3 (12.1)	47.3 (12.8)	−2.0	0.1	−1.5	−9.1, 6.1	0.68

[a] Difference in means was adjusted for baseline using ANCOVA.

Note. SD = standard deviation; CI= confidence interval; CG = caregiver; CR = care recipient; SR = self-rated; PR = proxy-rated; CSDD = Cornell Scale for Depression in Dementia; RAID = Rating Anxiety in Dementia; QoLAD = Quality of Life in Alzheimer's Disease; SCS = Social Connectedness Scale; QCPR = Quality of Caregiver Patient Relationship; PHQ = Patient Health Questionnaire; ZBI = Zarit Burden Interview; AQoL = Assessment of Quality of Life.

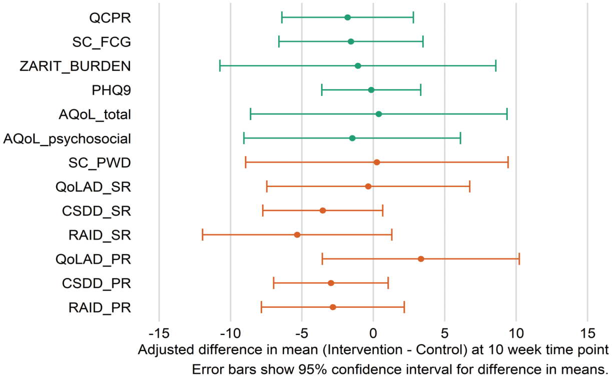

FIGURE 2.

Mean Differences Between Intervention and Control Groups at 10 Weeks. Green bars = caregiver measures, orange bars = care recipient measures (both self-rated and proxy rated). QCPR = quality of caregiver patient relationship; SC = social connectedness scale; CG = caregiver; CR = care recipient; SR = self-rated; PR = proxy-rated; PHQ = patient health questionnaire; AQoL = assessment of quality of life; QoLAD = quality of life in Alzheimer's disease; CSDD = Cornell scale for depression in dementia; RAID = rating anxiety in dementia.

the 10-week timepoint. Adjusted mean differences for all outcomes are presented in Table 3.

The summary statistics for all outcome measures at T0 and T1 are presented in Table 3. Caregiver burden was in the moderate range (21–40) for both groups and caregiver mean depression scores were also in the moderate range (10–14). Quality of life for the person with dementia was rated lower by the CG than the CR and did not change significantly.

Although between-group changes were not statistically significant, depression scores (CSDD) decreased for intervention participants and increased for control participants. Scores below 6 on the CSDD are associated with an absence of substantial depressive symptoms (Alexopoulos et al., 1988). Using this marker, CR participants in the intervention group moved from having symptoms of depression at baseline to not having substantial symptoms at 10-weeks on average. This result was supported by moderate-large effect sizes (self-rated $g = -0.7$, proxy-rated $g = -0.7$). Similarly, anxiety scores decreased (both self- and proxy-rated) for CRs in the intervention group, and the self-rated scores moved from the clinical anxiety range (12.7) to (7.8) within normal levels (Shankar et al., 1999). In contrast, self-rated anxiety remained in the significant clinical anxiety range at both timepoints for CRs in the control group. This result was supported by large (self-rated $g = -0.9$) and moderate (proxy-rated $g = -0.5$) effect sizes favoring participants in the intervention group.

Discussion

Due to recruitment difficulties, this study was underpowered and thus we were not able to conclusively answer the research questions regarding the effects of therapeutic choir participation on relationship quality and wellbeing outcomes for people living with dementia and their primary caregivers. However, as stated previously, an interpretative phenomenological analysis of qualitative data collected as part of this study, indicated that participants found choir participation to be cognitively stimulating, and fostered improvements to mood, social connection, and self-identity (Thompson et al., 2022). These qualitative findings align with the large effect sizes observed for decreases in anxiety and depression for care recipients in the intervention group and previous research indicating beneficial effects of music therapy on anxiety and depression (Baker et al., 2022; Moreno-Morales et al., 2020; Särkämö, 2018; Van der Steen et al., 2018; Werner et al., 2017). Anxiety and depression are significant issues for people living with dementia and thus it would be worthwhile further exploring the benefits of therapeutic choir participation in adequately powered future studies.

Study Limitations

Outcome Measure Limitations

In addition to the small sample size, there were several other limitations to this study, including floor and ceiling effects observed for many of the outcome measures used. This may suggest that caregivers and people with dementia who are willing and able to volunteer for research studies have a higher baseline level of wellbeing. Conversely, those who are more stressed, depressed, or experiencing relationship strain may be less inclined to enroll in a research study requiring active joint engagement in a social and musical intervention. Some of the measures were used without being piloted (i.e., CSDD, ZBI, AQoL-8D, SCS) due to changes necessitated by our feasibility study; however, these had been validated in other studies. Another limitation was the choice to use the Social Connectedness Scale, which was developed for young people and has not been validated for use in older adults. Participants also disliked the negative wording of the questions on this scale (e.g., "I have no sense of togetherness with my peers").

Design Issues Affecting Recruitment and Retention

Several limitations were evident in relation to study design, such as recruitment, withdrawal, participant burden, and sustainability, which impacted not only the statistical power of the study but also the viability of most choir groups. Recruitment was difficult due to a lack of communication options with eligible participants (despite a strong media drive and partnerships with referring organizations) and the high level of commitment required due to the study design. Such difficulties with the recruitment of community-dwelling family caregivers and people living with dementia align with other studies, where even accessing eligible participants was reported to be challenging (Baker et al., 2021, 2023; Sharma et al., 2022). Some similar issues, such as the perception of administrative burden and concerns regarding the burden of participation, have been previously reported as impacting recruitment in residential aged care dementia research also (Baker et al., 2020). The lack of an active, dyad-focused control condition was also a design limitation of the study. A further limitation related to the statistical analysis method used. As dyads participated together in small groups based on their site location, using a fixed or random effect for the choir group in the statistical model would have better accounted for potential clustering generated by the study design.

Finally, compounding the small sample size issue due to recruitment difficulties, attrition was high. This high attrition was due to illness, disease progression, difficulty recruiting enough participants to create a viable choir at some sites (which was discouraging to participants who had enrolled), and the burden of research participation, that is, completing assessments, attending intervention sessions for 20 weeks, and lack of engagement for waitlisted control participants. Anecdotally, participants from the three choirs that had sufficient numbers to continue for the full duration of the study found the program enjoyable, cognitively stimulating, provided social support, and wanted to keep attending post research, aligning with findings from our previous feasibility study (Tamplin et al., 2018).

Key Learnings

We have collated our key learnings about the viability and practicalities of conducting a large-scale RCT with this population of caregivers and people living with dementia in the community. We initially aimed to recruit 180 dyads to have sufficient statistical power to detect an intervention effect if one existed. The recruitment period was repeatedly extended to allow more time to reach this number, however, despite these accommodations, the final number for recruitment (61 dyads) was one-third of the required sample for adequately powered analyses, and this number dropped further due to high withdrawal rates.

Recruitment Challenges

We categorized the recruitment challenges we experienced in four main areas: (1) lack of communication options with potentially eligible participants, (2) lack of eligible couples associated with our partner organization, (3) reluctance of other providers to refer due to a perceived conflict of interest with the research partner organization, and (4) lack of flexibility of the RCT study design. At the time of recruitment, there were no databases or registers for people with a dementia diagnosis, and thus no direct way of alerting them to potential research opportunities. It is possible that our advertising methods (TV, radio, print media, social media) may have been inaccessible to some of our target population. Although we had a partner organization who assisted with recruitment, there were few consumers accessing the service who met the eligibility criteria for our study. This partnership also led to a reluctance from other providers to refer due to a fear of losing service users. Although we attempted to promote the study through various care providers, many declined as they felt referring to a program associated with a competitor was a conflict of interest. So despite our attempts to secure recruitment pathways and sustainability for the choirs post-study through partnering with a community-based aged care service provider, there were clear limitations to this approach.

Accessibility of Intervention

Due to the nature of an RCT research design, there was a lack of flexibility for participants to engage in the project in a way that was accessible to them. This highlights the tension between adhering to a strong research design (to address the lack of RCTs in this area) and providing an intervention that was accessible and manageable for participants who met our eligibility criteria. Several participants who expressed an interest, or even completed the initial assessment but withdrew before commencement, expressed that they were concerned about the requirement to attend weekly for 20 weeks. Some expressed that they felt this was too much pressure considering the unknown trajectory of the disease progression and potential illnesses and medical procedures expected during this timeframe. Others communicated that they did not want to be committed to the 20 weeks in case they needed to take a break. Although recruiters explained that missing some sessions would be acceptable, the majority of these participants still felt concerned about the length of the commitment. Aside from the length of the intervention period, participants reported no issues with the intervention content and delivery. However, it is possible that travel or transportation difficulties may have negatively influenced recruitment. In qualitative data from this study, participants commented that geographical proximity to choir location was a factor in joining Remini-Sing. Telehealth choir participation is an option to mitigate travel difficulties but poses other limitations, such as access to and confidence using technology, and insufficiency of online synchronous singing possibilities (Dowson & Schneider, 2021; Tamplin & Thompson, 2023). Yous et al. (2022) have suggested other program modifications that increase accessibility for this population, such as reducing the frequency of intervention and integrating research tasks into daily activities and routines. An open setting, where participants could attend (or not) as they wished, would be a more flexible approach, but would not provide a consistent dosage, which would make analysis of intervention effects difficult. Our qualitative analysis (Thompson et al., 2022) also highlighted a tension between choir participation enabling much-needed social connections (Theme 4) and the challenges with getting started (Theme 6) due to a range of reasons, including hesitancy to try something new and anxiety about singing, as well as the attendance pressure added by the RCT design and small group sizes.

Reasons for Attrition

As described previously, there was significant attrition during the study. Feedback from participants and observations from the research team highlighted the following factors that influenced withdrawals: high rates of illness and injury, low choir group numbers, and length of the waitlist period. Several participants, both caregivers and care recipients, experienced injury or illness that prevented them from continuing with the study. Participants in some choir groups expressed feeling pressure to attend due to the low group numbers (Thompson et al., 2022); when other participants withdrew, this left some choir groups with only one or two dyads. In the case of two choir sites, such low numbers compelled participants to opt to discontinue the groups altogether. Future research should ensure minimum group numbers at commencement (ideally at least 4–5 dyads) to mitigate this effect. Some participants who were allocated to the waitlist control group either opted to withdraw halfway through or had forgotten that they were part of the study when contacted for follow-up assessments. Some control participants expressed that their situation had changed by the time they were eligible to join the singing groups and they were no longer able to participate. This was another reason that we shortened the intervention length to 10 weeks. Lack of communication from the researchers with waitlisted control participants between weeks 1–10 was also cited as a challenge, as some participants were unclear on what was happening with the study during this time. In future research, we suggest weekly or fortnightly phone calls with control participants, as per the home-based HOMESIDE dementia study (Baker et al., 2019), in order to maximize engagement and retention.

Recommendations for Future Research

Despite the recruitment success in our feasibility study, from the results of the RCT, it seems clear that another pilot study is needed to further explore the recruitment rate in this population. Furthermore, it would be advisable to allow significant time and resources for the recruitment phase. Given the issues with conflict of interest perceived by care providers with referring to a program associated with a competitor, we recommend future researchers engage multiple partners to assist with recruitment and translation into practice. Other design recommendations include: statistically controlling for clustering by including a fixed or random effect for the choir group in the model, and ensuring measures have been validated for use in older adults or people with dementia. For example, the Social Disconnectedness Scale and Perceived Isolation Scale (Cornwell & Waite, 2009) or the Register-Connectedness Scale (Register et al., 2011) are measures that have been specifically designed to assess connectedness in older adults. We also recommend keeping in regular contact with control participants to remind them of their participation in the study and keep them engaged. This could be in the form of a fortnightly phone call check in.

Conclusion

Although relationship strain and suboptimal wellbeing have been reported for many people living with dementia and their care partners, this was not reflected in the small sample we were able to recruit for this study. Living with dementia and supporting a loved one living with dementia are known to be difficult and stress inducing. The aim of our intervention, and the overall study was to acknowledge and attempt to mitigate these negative effects and provide support and positive experiences to enhance wellbeing and promote flourishing. However, for several reasons highlighted in this paper, we were not able to recruit enough participants for a sufficiently powered quantitative analysis of results and thus generated no statistically significant findings. Despite this, we found medium and large effect sizes for anxiety and depression, indicating a potential intervention effect of therapeutic choir participation for people living with dementia that should be explored in future research. Methodological issues experienced, such as low recruitment rates and high attrition, floor and ceiling effects on standardized measures, intervention/waitlist length, and control participant engagement, should be considered when designing future studies with this population. Dementia can be an all-consuming experience, and the extra effort to participate in additional activities outside the home (even programs perceived as beneficial) may be too much for many to attempt. Despite this, the dyads who did engage in the therapeutic choir intervention reported it to be a valuable, positive, and enjoyable experience that afforded them personal and relational benefits (Thompson et al., 2022).

Supplementary Material

Supplementary material is available online at *Journal of Music Therapy*.

Author Contributions

Jeanette Tamplin (Conceptualization [Lead], Data curation [Lead], Formal analysis [Lead], Funding acquisition [Lead], Investigation [Lead], Methodology [Lead], Project administration [Lead], Resources [Lead], Supervision [Lead], Visualization [Lead], Writing—original draft [Lead], Writing—review & editing [Lead]), Zara Thompson (Investigation [Supporting], Project administration [Supporting], Writing—review & editing [Supporting]), Imogen Clark (Conceptualization [Supporting], Investigation [Supporting], Methodology [Supporting], Project administration [Supporting], Writing—original draft [Supporting], Writing—review & editing [Supporting]), Kate Teggelove (Investigation [Supporting], Project administration [Supporting], Writing—review & editing [Supporting]), and Felicity Baker (Supervision [Supporting], Writing—review & editing [Supporting])

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