

Abstract

Positive effects of music therapy for people with dementia and their family carers are reported in a growing number of studies. However, small sample sizes or low recruitment rates often limit the success of these research studies. More adequately powered evidence-based studies are needed to impact policy and funding in dementia care. This systematic review examined recruitment strategies in music therapy clinical trials involving people living with dementia and/or their family carers. Eligible studies described enrolment, consent, accrual, or recruitment methods as well as recruitment or consent rates. Thirty studies with a total of 1,192 participants were included. Recruitment and conversion rates in residential aged care facilities (RACFs) (14 studies) were substantially higher than in community-based studies (16 studies). Whereas studies in RACFs most commonly recruited participants through staff approaching residents face-to-face or conversing with residents' legal guardians, community-based studies utilised a vast array of strategies, including staff referral, demonstrations/information sessions by researchers, advertisements, and direct contact with residents. Recruitment rates are likely to be higher when recruiters have an existing relationship with potential participants and when an independent third-party dementia organisation is involved. RCTs led to equally or greater recruitment conversion rates than other designs. Findings suggest that recruitment in dementia trials is complex, challenging, and needs thorough planning and consideration to be time- and cost-effective. Future studies should include reporting of recruitment strategies, enrolment rates and related aspects so that researchers can better design recruitment strategies and estimate resources needed to reach the target sample size.

Introduction

Music therapy is a health treatment and a supporting resource for people living with dementia and their family caregivers. Music engagement during singing, playing simple instruments, physical movement or dancing to favourite music can create opportunities for reminiscence, arousal regulation, physical and cognitive activation and support social interaction (Ridder, 2003; Ridder, 2005). This engagement with music strengthens relationships between people living with dementia and their environment and may improve quality of life for caregivers (Hsu et al. 2015).

Several studies show positive results on emotional wellbeing, reduction of anxiety, and improved quality of life. The Cochrane review (van der Steen et al., 2018) confirmed the positive effects of music therapy in dementia care on reducing depressive symptoms and improving overall behavioural problems. Recent systematic reviews (Moreno-Morales et al., 2020; Lam et al., 2020) suggest music therapy improves memory, verbal fluency, reduces anxiety and apathy, and has short-lasting effects on the quality of life of people with dementia. However, these reviews revealed no significant effects of music therapy on agitation and aggression, or on improvements in cognitive and daily functioning. No long-term music therapy effects were reported (van der Steen et al., 2018; Moreno-Morales et al., 2020; Lam et al., 2020). These reviews show the therapeutic potential of music in dementia care, but conclusions are limited by the small number of fully powered robust clinical trials. Small sample sizes were one of the main limitations of included studies in the reviews with low recruitment rates often the cause of underpowered studies.

Randomised controlled trials (RCT) have long been argued as the gold standard of evaluating the effects of health interventions (Hariton & Locascio, 2018) including studies of music therapy. However, the success of such trials is often hindered by low recruitment rates (Walters et al., 2016). Despite researchers' best efforts to recruit, approximately 50% of clinical trials fall short of reaching their recruitment targets (Sully et al., 2013), with as many as 22% of studies recruiting less than 80% of their target sample size (Walters et al., 2016). Recruitment strategies that fail to generate participant enrolments, reduces study power, and the likelihood of detecting significant effects (Swanson & Ward,

1995), not to mention causing delays in completing the study, increased costs, and can lead to failure to complete trials (Walson, 1999). Certainly, in the music therapy literature, limited generalisability of results is often attributed to low participant numbers (Porter et al., 2014).

Many factors may impact the uptake of trials by potential participants. Firstly, study design may influence recruitment success. A systematic review of clinical trials that compared different recruitment strategies, found that consent rates were higher for nonblinded trial designs (Caldwell et al., 2010). More people were willing to consent to participation when the trial was a noninferiority study compared with a placebo-controlled study. Rates of consent were higher when participants had a greater chance of receiving the experimental treatment or when participants could self-select into the treatment of their choice (non-randomised).

Recruiter characteristics have also been found to impact successful recruitment. Larkey et al. (2002) compared the success rate of recruitment between trained and untrained recruiters. Those recruiters with extensive training had a statistically higher success rate in recruiting participants to the study when compared with those who lacked training. In a review by Caldwell et al. (2010), the authors concluded that when examining the amount of contact recruiters had with potential participants had no statistically significant effect on enrolment success. Indeed, the trend was that there was a lower enrolment with increasing contact by the recruiter.

Participant incentives has received attention as a way to increase enrolment in studies. Incentives could include receiving payment, store vouchers, or an offer to receive the target intervention at the conclusion of the study if the participant was allocated to the comparative treatment or standard care. The review by Caldwell et al. (2010) showed that while incentives increased rates of consent to participate, the monetary amounts (from US\$100 to US\$2,000) did not make a statistical difference irrespective of the risk and severity of potential adverse effects or of being assigned to standard care.

A review of six recruitment trials that used mail-outs of recruitment material (Caldwell et al., 2010), identified five methods – 1) the use of a personal letter inviting participation, 2) the use of bulk-mailing, 3) an advanced postcard alerting participants to anticipate receiving recruitment packages in the

near future, 4) a reminder phone call for non-responders following mail-outs, and 5) increasingly intensive phone and mail contact with potential participants following initial mail-out of recruitment letters. The review concluded that none of these techniques were more effective than others. The degree of complexity of the study descriptions contained in recruitment letters did not affect recruitment rates. Plain language statements did not lead to greater consent rates than those where language was more complex or contained more detailed content.

In one study by Weston et al. (1997), advertising the trial via video did lead to higher levels of study participation when compared with a general written invitation to participate. Caldwell's et al. (2010) review also concluded that there was no difference in consent rates when the clinical trial managers read and explained the details of the study when compared with mailing standard recruitment packages containing plain language statements and consent forms.

Raising awareness of the studies using a combination of community-based strategies is one way to maximise enrolment. In a study recruiting older people from the community living in retirement homes (Duckham et al., 2018), posters displayed in central areas of the village were effective as well as the research team offering on-site presentations which highlighted the benefits to the individuals and society of study participation. As reported by Goldman et al. (2019), mail-outs and telephone approaches led to the lowest enrolment rates (1.2%), followed by media and advertising strategies. The most effective approach was having a direct referral from a health practitioner and the provision of information and education sessions (27% and 52% respectively). Liu et al. (2018) reviewed recruitment strategies used in mental health studies and identified additional approaches other than those mentioned in the previous studies including - information provided by charity organisations, web-based adverts, radio adverts, bus adverts, newspaper adverts, Google and Facebook adverts, online forums, links from healthcare websites, online community notice boards, and group emails. The review concluded that it was difficult to determine which was the most effective strategy.

Friedman et al. (2015) identified potential strategies for subsequent participation and testing, by first conducting interviews and focus groups of people living in the community. Their study aimed to

identify what were the perceived motivators, enablers and barriers to study participation. Findings suggested that major barriers included fear of adverse or side effects of participation in the study, a lack of understanding about what the trial was about and aiming to test, a sense of mistrust in the researchers, and having limited time available to participate. Participant payment was identified as being the highest motivator for participation surpassing the potential for the intervention to be of significant benefit. Those interviewed highlighted that community organisations such as church communities, word of mouth, and advertisement in the media were most likely the best approaches to recruit.

In another study, interviews with older adults about participation in research also identified several barriers and motivators (Marcantonio et al., 2008). There was high preference by study participants to participate in research from their own home rather than having to travel to another location (98%) and 28% suggested they would not consent to participate if they had to travel in order to participate. The shorter the study length, the higher the motivation to participate with longitudinal studies being a disincentive to participate in 10% of cases. Similarly, studies involving interviews of longer than 90 minutes was a barrier to recruitment for 24% of those interviewed. Overwhelmingly, most participants believed the contribution to knowledge and society was the primary motivation for participation. Other motivators included the potential for personal benefit, and giving older people some purpose, something to do. Incentives such as free meals or stipends were not motivators to participate however support such as provision of transportation and free parking (90%), flexibility in appointment times (76%), and provision of educational materials (46%) were strong incentives.

We found only one music therapy study that has partially reported data on recruitment strategies and learnings on what are the most effective approaches to convert eligible participants into enrolled participants. Baker et al. (2020), examined resource use in recruiting, assessing, and delivering interventions in people living with dementia in residential aged care facilities (RACFs). Their recommendations for effective recruitment conversion strategies were based on 316 enrolled participants from 666 screened collected over 18 months. They recommended firstly that researchers include in the study budget, funding to hire foreign language translators who can be present during recruitment to ensure

those residents and next of kin from different backgrounds can fully understand the plain language statement before consenting to participation. They also recommended that plain language statements be simplified and if necessary, to make an argument to ethics committees to do so, to increase understanding of the study intentions and expected involvement. Finally, the researchers recommended that recruiters practice therapeutic listening when first making contact with potential participants to build rapport with participants and their next of kin, listening to their stories, concerns, and struggles. This increases the likelihood of converting to an enrolment.

To date, there has been no systematic review examining recruitment strategies used in music therapy trials nor a review of studies whose target sample sizes were met or not met. The findings from this review are intended to inform future research in music therapy with people living with dementia and/or their family carers, enabling researchers and clinicians to design and carry out research that is both effective and ethically sound. For us, a second motivation for this review was to prepare for a large adequately powered music therapy RCT (Baker et al., 2019) that will be delivered across 5 countries. We sought to systematically review the music therapy literature to identify the most effective recruitment strategies used by researchers aiming to maximise recruitment of people living with dementia and/or family caregivers of people living with dementia. We were interested to learn about how long recruitment periods were set for, and how recruitment rates compared for randomised and non-randomised trials. We also sought to identify whether additional strategies (e.g. use of music engagement) other than those identified in other reviews of recruitment strategies were being used and with what level of success.

Research Questions

Our research sought to answer the following questions about recruitment:

1. What percentage of music therapy studies of people living with dementia and/or caregivers of people with dementia, met their target sample size?
2. What are the most successful recruitment methods adopted in music therapy clinical trials of participants who are living with dementia and/or their family caregivers?

3. Are there differences in recruitment success which are dependent upon study context?
4. Are some study designs more likely to lead to higher or lower recruitment rates?

METHOD

Literature Searches

Studies were identified from CINAHL, EMBASE MEDLINE, PubMed, and PsycINFO (January 1st 2000 to February 28th 2020). The databases were searched using text words and subject headings ‘music therapy or music intervention* or music or sing or singing’ AND ‘dementia or Alzheimer’ or ‘family caregiver* or family carer* or informal carer*’ combined with ‘random* or trial*’ all with unlimited truncations.

Eligibility Criteria

Studies involving music therapy interventions that focused on exploring the impact or experiences of people living with dementia and/or their family caregivers, were eligible for inclusion into the study. All study designs were eligible for inclusion. Where more than one publication of the same study existed, the publication with the most complete data was included.

Studies meeting the following criteria were eligible:

- 1) Studies included music intervention(s) designed and delivered by a credentialed music therapist.
- 2) Study participants were people with a diagnosis of dementia and/or were family carers of people living with dementia. Dementia diagnoses included mixed dementia, Alzheimers, Frontotemporal dementia, Lewy body Disease, and Vascular Dementia,
- 3) Studies were clinical trials studying the effects of an intervention – randomised controlled trials, parallel designs, cross-over designs, quasi-experimental designs and non-randomised designs.
- 4) Enrolment, consent, accrual, recruitment or participation methods or strategies were described
- 5) Recruitment and/or consent rates were described
- 6) Studies published in English, Norwegian, Swedish, Danish, German, Polish, Mandarin, French

Portuguese, and Spanish as authors of this review were fluent in one or more of these languages.

Studies were excluded if they did not describe recruitment methods, recruitment rates, included only formal caregivers, or included caregivers caring for people who did not have a diagnosis of dementia.

Cohort, observational, case-study and qualitative studies were excluded.

Study Selection

Seven reviewers (FB, TW, JP, KJ, AB, LB, AK) independently screened study title and abstract for potential eligibility (two reviewers per article). Following initial screening, discrepancies were discussed among reviewers and a decision to include or exclude was made. Full text reviews were then made by two reviewers per article to check for eligibility. Discrepancies were discussed by and decisions made as to whether or not to include these articles in the review. Rayyan QCRI systematic review software (Ouzzani et al., 2016) was used to track reviewers and decisions made.

Data Extraction

A data extraction form was developed to guide the identification of relevant information. Five reviewers from the team (JP, TW, KJ, AB, AK) extracted data from the included studies, and one other reviewer (FB) checked for accuracy. If a discrepancy was detected, this was discussed and resolved with reference to the full text of the relevant article. Data were extracted without blinding to authorship on reference details; country of study; year; study objective(s); study design; subject details (sample size, demographic details, inclusion and exclusion criteria); qualifications of recruiters and recruiter training; fidelity checking of recruitment approaches; recruitment methods, inclusion of incentives; consent rate, attrition after randomization, music intervention details; control and comparison interventions; duration of study period; total duration of participant time-commitment; setting (home, study-site); and outcome measures. Extracted data were recorded in an excel spreadsheet.

Risk of Bias

The full PEDro scale (Cashin & McAuley, 2020) was used to evaluate the quality of the included studies. All 11 criteria - eligibility, randomisation, concealment, similarity at baseline, blinding of participants, therapists and assessors, key outcomes, intention-to-treat, between group comparisons for at

least one key outcome, and measures of change and variability – were assessed by two researchers from the research team. Disagreements between assessments were discussed with a third member of the team and a final score arrived at by consensus. The quality assessment was used to determine whether there were any trends in research design that impacted recruitment rates and approaches.

Data Synthesis

The primary outcome of interest was the consent rate for each recruitment strategy. Because studies differed in definitions of consent rates, where possible we recalculated the consent rate of each recruitment method by dividing the number of participants exposed to the recruitment method who actually consented for clinical study participation (when known) by the total number of potential participants exposed to that method. For studies where information was insufficient to calculate consent rates, other measures of consent success described in the study were reported. Studies were categorised according to strategies, and the number of strategies used. We ranked the success of strategies based on the numbers of participants recruited and the speed with which participants were recruited.

Descriptive synthesis of the data was performed by looking at the relationship between consent and retention rates and a) country of study, b) recruitment approach, c) study design, d) required contributions of participants (total hours, length of study, frequency of required participation), e) site of participation (home vs study site), f) type of music and comparator interventions, and g) differences between studies of carers, people with dementia, and both. Following the synthesis, conclusions about the most effective strategies for participation in music therapy clinical trials were formed.

RESULTS

Study Selection

The search resulted in 3,567 texts, with an initial library of 2,007 records following the removal of 1,560 duplicates. From the initial screening, there was disagreement by two reviewers for 340 articles. 333 of these were resolved by a third reviewer and the remaining seven went to a fourth reviewer until final decision to include/exclude was made. In the full-text review, 394 articles were included. Review of

full texts resulted in fair agreement between two reviewers with 11 inclusions, 329 exclusions and 54 requiring further discussion (86.3% agreement, $\kappa = 0.21$). Of these, 19 were included and 35 were excluded (Figure 1). Finally, 30 studies were included in this review.

<<INSERT FIGURE 1 ABOUT HERE: **Figure 1. PRISMA Flow diagram: Study selection**>>

Study Characteristics

Sample sizes ranged from 15-104 for RACF studies ($M = 52.43$, $SD = 37.8$), and from 5-45 for community-based studies ($M = 28.62$, $SD = 21.2$). All studies with the exception of Baker et al. (2018) included people with dementia. Baker et al. (2018) focused on family caregivers of people with dementia. Four community studies included both carers and people living with dementia. Nine studies were RCTs (fully powered or pilot), six in RACFs and three in community settings. Twenty-two studies (11 in both community and RACFs) were studies of group music therapy.

Risk of Bias

Of the 330 items assessed by two raters on the PEDro Scale, there were 196 occurrences of rate agreement in an item meeting the item criteria, and 112 occurrences where raters agreed the study did not meet the item criteria (93.3%, $\kappa = 0.857$). For 22 items, raters initially disagreed. Disagreements were resolved through discussion. Using Cashin and McAuley's (2020) criteria of quality (scores of 0-4 poor, 4-5 fair, 6-8 good, and 9-10 excellent), the mean score on study quality was 4.13 ($SD = 2.0$) indicating studies were of fair quality. Eight of the studies were ranked as of good quality, none reached a score of ≥ 9 points (Table 1). None of the 30 studies blinded participants or therapists delivering the intervention, eight studies involved blinding of assessors. Fourteen trials did not provide results for all outcome measures, and therefore demonstrated possible outcome-reporting bias.

<<INSERT TABLE 1 ABOUT HERE: **Table 1. Quality checking using PEDro**>>

Synthesis of Results

For clarity in reporting and to aid in the synthesis of the findings, the reporting of studies has been divided into studies within Residential Aged Care Facilities (RACFs) and in community settings.

Studies in Residential Aged Care Facilities

Of the 30 studies, 14 were delivered in RACFs (Table 2). When specified, the mean recruitment conversion rate was 89% (SD = 0.11) with rates ranging from 73-100%. Recruitment conversion did not seem to be less for RCTs, in fact all RCTs were above 79%. Recruitment rate ranged between 5.1 - 21 enrolments per month (M = 12.6 per month, SD = 6.8) with recruitment periods ranging from 1.8 to 6 months (M = 2.93, SD = 1.8). Attrition rates varied from 0-46% (M = 16%, SD = 17%) with highest attrition rates occurring for longer study trials. Most common recruitment methods were RACF staff approaching potential residents either face to face and/or by talking with legal guardian about the study. Consent was provided either by participants themselves or by proxy. Only three studies specified a target sample size, two of these met or exceeded their target. One study reached 89% of its target sample size.

<<INSERT TABLE 2 ABOUT HERE. Table 2. Recruitment trends of music therapy studies delivered in residential aged care facilities. >>

Community based

There were 16 studies that were community based (Table 3). Recruitment conversion rates were reported in seven studies and ranged from 48-100% (M = 71%, SD = 18%). Recruitment conversion rates were reported in two RCTs and five non-randomised studies. These conversion rates were higher for RCTs (72% and 91%) than non-randomised studies (48%, 53%, 60%, 71% and 100%). Recruitment rates were between 1.3-14 participants per month (M = 5.1 per month, SD = 4.2), with recruitment periods varying from one month to two years. Attrition rates ranged between 0-57%, (M = 2.7%, SD = 8.7%). It was noted that a vast array of strategies were utilised in community-based studies, most frequently staff referral, demonstrations/information sessions by researchers, advertisements, posting flyers, and direct

contact with residents. Four studies used two or more methods for recruiting. Consent was provided either by participants themselves or by proxy.

<<INSERT TABLE 3 ABOUT HERE. **Table 3. Recruitment trends of music therapy studies delivered in community settings.** >>

Comparisons between RACFs and Community

In comparing the studies across two different contexts, it was noted that recruitment rates in RACFs were more than double the community-based studies, and the recruitment conversion rates were also substantially higher for RACFs. Consent was more often provided by proxy in RACF studies than in community-based studies. Attrition rates were similar across both contexts. The RCT design did not appear to limit conversion to enrolments in either context. Attrition rates were similar in RCTs ($n = 10$ studies, $M = 15.8\%$, $SD = 16.3$) and non-randomised studies ($n = 20$ studies, $M = 19\%$, $SD = 19.9$).

DISCUSSION

The results of the 30 studies reviewed suggest that recruitment of participants (caregivers and persons living with dementia) is complex, challenging, and influenced by a number of factors that may interact during recruitment. Only three of the included studies state a target sample size. This might indicate that it is difficult to estimate participant numbers in research with people with dementia and/or that it is difficult to reach the target sample size. Further, 12 quasi-experimental studies and two RCTs of the 30 studies reviewed failed to report on conversion rates in recruitment. Reasons for this may include missing or inaccurate data collection or record keeping regarding recruitment processes. It is also possible that recruitment conversion rates may have been recorded, but not reported and published. Analysis of study designs within the group of studies that provide these data showed that conversion rates were not lower for RCTs than for other designs (quasi-experimental and non-randomised trials). Both RCTs and non-randomised group trials showed wide ranges in conversion rates. Across settings, RCTs had a mean

rate of 91.5%, while non-randomised and quasi-experimental trials reported a mean rate of 71.25%. This finding might be surprising, as researchers, clinicians and participant representatives may consider the presence of a control group, and potential assignment to this, the cause of recruitment difficulties and attrition in studies with human participants (Huibers et al., 2004; Hughes-Morley et al., 2015). However, and in contrast to Caldwell et al (2010), the finding of this review suggests that randomisation to a control group in music therapy research does not have a negative impact on recruitment. An explanation for this discrepancy might be if the treatment/intervention were offered to control participants after the study or not, possibly motivating them to participate – even as control participants. However, we could not find enough information to determine if this was the case. Perhaps other factors, or a combination of interacting ones, may influence enrolment and conversion rates in addition to the inclusion of a control group or condition. Additionally, attrition rates did not reveal any clear differences between RCTs and quasi-experimental designs, with studies from each type of design reporting 0% attrition and rates of >20%. Higher attrition rates are not surprising in research with people living with dementia, considering the progressive nature of the disease. Furthermore, people with dementia are mostly older adults who might also suffer from other age-related illnesses. Therefore, it is likely that a proportion of participants in these research studies will be lost due to changes in living situations and care arrangements, hospital admissions, and deaths of the people with dementia or their family caregivers.

Study location appeared to be a factor influencing recruitment. Studies recruiting at RACFs had higher recruitment and conversion rates than those conducted in the community. One interpretation of this finding is that it is easier to recruit from settings where groups of participants are in one place. We can infer from this that recruitment is bolstered by recruiting from groups of participants that broadly match selection criteria. These groups can be found in settings and treating institutions, but also in the community in support groups and choirs that meet regularly. Another way in which potential participants are grouped is through online databases of willing research volunteers, for example Join Dementia Research in the UK. Having access to willing participants in groups through institutions or databases increases the size of the recruitment pool. It is logical to assume that the larger the size of any pool or

cohort of participants, the higher the recruitment rate will be. However, the capacity of the recruiters must also be taken into account. Higher numbers of recruiters spending more time on identifying potential participants and screening them may yield higher rates of recruitment and enrolment. Another important consideration is that the person with dementia may be at a later stage of the disease than he/she was when registered on the online database. His/her situation may have changed and the record may not be updated. Therefore, it may be important for the researchers to know how often the database is updated and what is the process for this.

Although, selective grouping of participants by treating institutions, care settings or databases might have a positive effect on recruitment and the efficiency of recruitment processes, there are other factors associated with location of recruitment that could explain the higher recruitment figures for RACFs. For instance, it is important to note that one study reported a high preference for participants to be studied in their own home (Marcantonio et al., 2008). This might have practical reasons such as not needing to travel to take part in the research. As Friedman et al. (2015) noted, lack of time was perceived as a major barrier for research participation. For people living in RACFs they might also feel safer to participate because they are surrounded by qualified personal who are supporting them. Related to this we can notice that at RACFs, the recruiters were often staff at the institution. These consisted of social workers, leisure staff, nurses, administration staff, and care home staff. These workers may have already developed a rapport with the potential participants through working with them as part of their role in the participants' lives. This provides the worker with specific knowledge about eligibility of the potential participants prior to screening. It allows for appropriate targeting of potential participants who are likely to enrol. Further, participants may feel safer to consent to participate because they are speaking with someone they are familiar with and trust. This sense of safety and trust could be of particular importance to persons living with dementia, as a sense of cohesion might be challenged by memory loss and disorientation (Kitwood, 1997). Hence, recruitment efforts can become more efficient and yield higher conversions to enrolment of eligible participants. Goldman et al. (2019) listed direct referral from a health practitioner as one of the most effective approaches. In community studies, the recruiters consisted of

researchers, day care managers, neurologists, clinic staff and care staff. Some of these workers are likely to have developed a rapport with the participants prior to taking on a role as a recruiter for a study. However, some, researchers in particular, may be meeting the potential participants for the first time due to recruiting them for the study. In these cases, the recruiters must develop a rapport with the potential participants as part of the recruitment process. This may also explain the lower recruitment and conversion rates for studies with participants in the community.

Another factor that may have an impact on recruitment, in particular conversion from eligible to enrolment, is consent procedures. In research involving people living with dementia, it is important to consider if a proxy consent is necessary due to participants' cognitive impairment. In cases of proxy consent, it is also important to ensure that the participants themselves are given the opportunity to have their say by either expressed or implicit assent. Providing opportunities for either written or verbal consent or assent could be important to ensure participant are heard, and also providing these opportunities regularly during the study to accommodate changes in their willingness to participate. Comparing studies in RACFs and community settings, consent was more often provided by proxy (legal representatives, close relatives etc.) in RACFs, while self-consent was more often the case in community settings. This is not surprising as people living in RACFs might have a later stage dementia than people living in communities. Many of the studies had a combination of written and/or verbal self-consent, proxy consent and/or participant assent without specifying numbers for each. From the information provided we could not see any clear tendencies in whether self-consent, proxy consent or a combination of both affected enrolment in either direction.

How information is provided prior to consent might also affect recruitment. Although Caldwell et al. (2010) found that plain language statements did not lead to greater consent rates, Friedman et al. (2015) listed lack of understanding of the study as a major barrier for participating in research. Baker et al. (2020) recommend simplifying plain language statements and to have a translator present if the participants have a foreign language background. For people living with dementia, cognitive impairment might affect their ability to understand complex and lengthy information letters or detailed verbal

descriptions. To ensure understanding, the information provided might need to be adjusted to each participant's cognitive level. Verbal explanation, meeting with the participants, written information letters, information sheets or similar providing information about the research are among the consent procedures described in the included studies. One of the studies (Clements-Cortes, 2015) included two types of information letters: consent-to-participate and assent-to-participate. But how these letters differ is not described. Across the studies little detail is provided about how the information was presented and if it was designed with people living with dementia in mind. This makes it difficult to know whether recruitment was affected by this issue.

There are also other differences between RACF and community settings that might impact recruitment and contribute to understand the differences in recruitment rates. People living with dementia in the community might be at an earlier stage of dementia than those living in RACF, something the higher number of proxy consent in the RACF studies also indicates, although there might be cultural differences between countries. For many, accepting or coming to terms with the dementia diagnosis may be difficult and take some time. Lack of acceptance of one's diagnosis would likely affect willingness to join a dementia specific study. Stigma could also be a relevant factor negatively impacting this. Significant stigma is associated with dementia particularly in early stages of the disease (Bartlett, Milne & Croucher, 2019), suggesting that stigma is more present in community settings than in RACFs and might in a greater degree impact recruitment. How to meet these challenges is complex and is something that could be explored further preferably in collaboration with people with lived experiences.

Friedman et al. (2015) listed limited time as one barrier to participation in research studies. Intervention frequency and duration did not appear to reveal a clear pattern in the 30 studies reviewed here. These factors may affect attrition rates because participants experience the intervention after enrolment. However, attrition may also be affected by other factors, for example death of participants, progression of dementia, anxiety during assessment or data collection procedures, and not receiving the intervention due to being in the control group.

Recruitment methods for engaging participant groups included mailing information, leaflet handouts, calling potential participants by telephone, approaching them in person, presentations to groups, displaying posters, and direct referrals by staff members. Participants were also recruited by contacting their carers. As recruitment rates varied within these methods, it is difficult to compare them and to draw conclusions about which recruitment methods are more successful than others. However, and consistent with Goldman et al (2019), the highest recruitment rates were reported in studies involving referrals by staff and researchers explaining the study to potential participants. The lowest recruitment rate was reported in a study in which the carers were contacted by telephone or in person.

Across the 30 studies reviewed, there was inconsistent reporting of some of the categories defined in this review. This is not a comment on the quality of the research studies, but it is a statement about the missing data that, if present, would enable more confident statements and comparisons to be made. The categories which were reported inconsistently include recruitment strategies, recruiter details, recruitment rate, recruitment period, consent procedures and conversions of eligible to enrolled participants. This makes it difficult to draw conclusions about recruitment strategies and their effectiveness, and limits what other researchers can learn from the studies regarding successful recruitment. For instance, Larkey et al. (2002) found that trained recruiters had a higher success rate in recruiting participants than those who lacked training. The training of recruiters is not reported on in any of the studies and, therefore, it is not possible to conclude whether or not it is a relevant factor influencing recruitment in these studies.

This review focused on music therapy studies for people living with dementia and/or their family carers, and excluded a large number of music intervention studies delivered by other health care professionals such as nursing staff. We chose to keep the review focused on music therapy but in doing so, there were numerous studies of people living with dementia participating in music interventions that may have presented additional data that might have added to our understanding of the most effective and cost-effective recruitment processes. Future reviews might consider pooling all studies that included music interventions irrespective of who designed and delivered the interventions and compare and contrast the recruitment strategies used. Another limitation of our review was that there was insufficient

data to determine which methods - mailouts information, direct approaches, presentations, referrals etcetera – were superior to others. Future studies testing different recruitment methods would enable the most effective and cost-effective methods to be determined.

Conclusion

In general, researchers of music therapy trials are not paying much attention to recruitment details in their reporting of studies. Seventy-two music therapy studies were omitted from this review because there was no reporting on recruitment strategies, recruitment periods, and conversion rates. In the studies reviewed, reporting on recruitment was often incomplete or inconsistent which limits the possibilities to learn from previous research.

Based on our review, we offer the following recommendations for successful recruitment:

1. Recruitment rates are likely to be higher when brokered through a third party such as a RACF, community organisation where there is a database of potential participants, or national research databases of willing research volunteers.
2. Recruiters such as healthcare workers who have an existing relationship with potential participants may be more successful and more efficient in recruiting and converting potential participants into enrolled participants.
3. As discussed by Baker et al. (2020), where researchers are responsible for recruitment, developing rapport may be an important factor in increasing likelihood of conversion to enrolment.

Conducting research studies with people with dementia and/or their family caregivers poses several challenges that are specific to this participant group and need to be considered before setting up the study and deciding on recruitment strategies. These challenges include the progressive nature of the disease, difficulties around capacity to consent, stigma and related difficulties with acceptance of the disease, and

difficulties to reach this participant group in the community. Owing to these challenges, it is important that future research studies include more detailed reporting so future researchers can adopt the most successful strategies. However, we acknowledge that word count limitations in several journals may pose a challenge for how much details can be included. Prioritising what to report might be necessary, and we therefore suggest the following guidelines for reporting recruitment in future research studies:

- 1) All studies should comment on rates of conversion from expressions of interest to enrolments.
- 2) Studies should summarise main strategies for recruitment: how the potential participants were contacted, where the recruitment activity took place and if a carer/family member or other health practitioner was present or involved.
- 3) Where more than one recruitment strategy was utilised, it will be useful to specify which strategy, if any, was the most successful.
- 4) Where possible, studies should record and report reasons for refusal and reasons for consenting to participate.

This information may guide research design in the future, help researchers understand more about participant experiences and decision-making, and possibly influence the types of interventions offered. Increasing reporting of recruitment rates and strategies could be useful for other researchers to a) better estimate the time and manpower required to recruit the minimum number of participants to ensure study power, and b) better estimate the funding required to complete recruitment. With the recent increase in funding of large multi-country music therapy clinical trials in both community (Baker et al., 2019) and RACF (Gold et al., 2019) contexts, efficient and cost-effective strategies that allow researchers to meet their target sample sizes is imperative if the profession is to succeed in completing evidence-based studies that could impact policy and funding of music therapy in dementia care.

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Tables and Figures

Figure 1 - PRISMA flow diagram: study selection

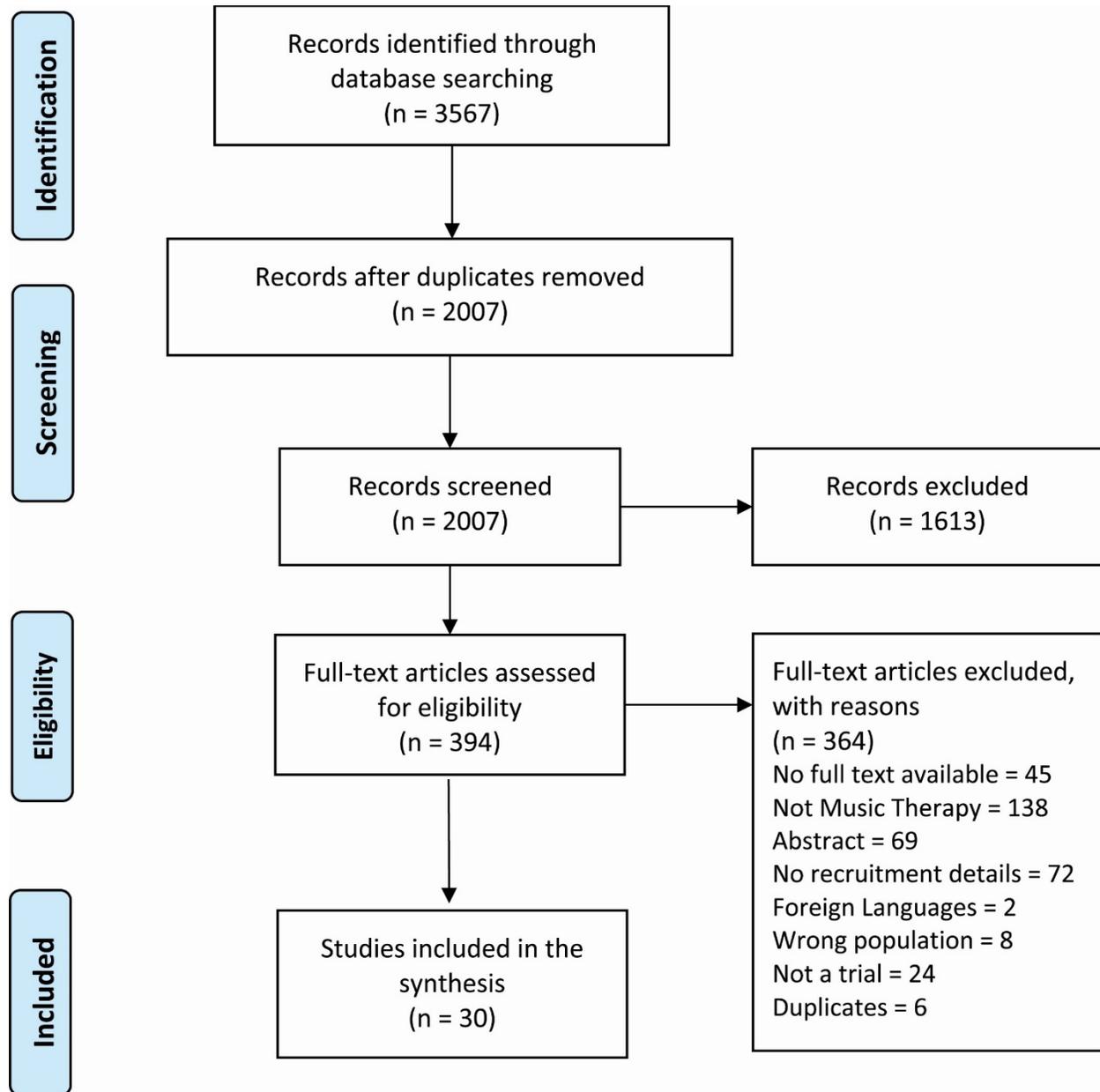


Table 1 - Quality Checking Using PEDro (Cashin & McAuley, 2020)

	PEDro Item Number^a												
Reference (Year)	1	2	3	4	5	6	7	8	9	10	11	Total/10	
Baker et al. (2012)	√	x	x	x	x	x	x	√	√	x	√	3/10	
Baker et al. (2018)	√	x	x	√	x	x	x	√	√	x	√	4/10	
Berger et al. (2004)	√	x	x	√	x	x	x	x	√	√	√	4/10	
Bruer et al. (2007)	√	√	√	x	x	x	x	x	√	√	√	5/10	
Choi et al. (2009)	√	x	x	√	x	x	x	√	√	√	√	5/10	
Chu et al. (2014)	√	√	√	√	x	x	x	√	√	√	√	7/10	
Clair (2002)	√	x	x	x	x	x	x	√	√	x	x	2/10	
Clair et al. (2005)	√	x	x	x	x	x	x	√	√	x	x	2/10	
Clements-Cortes (2013)	√	x	x	x	x	x	x	√	√	x	x	2/10	
Clements-Cortes (2015)	√	x	x	x	x	x	x	√	√	x	√	3/10	
de la Rubia Orti et al. (2018)	√												

Note. ^aPEDro items: 1. Eligibility criteria were specified. 2. Subjects were randomly allocated to groups. 3. Allocation was concealed. 4. The groups were similar at baseline regarding the most important prognostic indicators. 5. There was blinding of subjects. 6. There was blinding of all therapists who administered one key outcome. 7. There was blinding of all assessors who measured at least one key outcome. 8. Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups. 9. All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by "intention to treat." 10. The results of between-group statistical comparisons are reported for at least one key outcome. 11. The study provides both point measures and measure of variability for at least one key outcome. √ indicate the criteria was satisfied. x indicates the criteria was not met Item 1 not included in total score.

Table 2 - Recruitment Characteristics of Music Therapy Studies Delivered in Residential Aged Care Facilities

Publication	Study		Intervention		Recruitment Details						
Author (Year)	Sample Size	Design	Length	Type	Strategies	Recruiter	Rate per Month	Period (Months)	Conversion of Eligible to Enrolled	Attrition Rate	Consent Details
Bruer et al. (2007)	28	RCT, crossover	Weekly, 45 min, 8 weeks	Group	Hospital staff met with each patient or legal representative to explain study	Social workers	18.5	1.8	97%	0	Self-consent or proxy consent (authorized representative) after social worker met with them to explain the research
Chu et al. (2014)	104 (target 62)	RCT, parallel group	2× weekly, 30 min, 6 weeks	Group	Provided eligible RACF residents and legal representatives authorized with detailed explanation of study and invitation to participate				NR	3%	Written/verbal self-consent and written proxy consent (authorized representative) after being provided a detailed explanation of the study
Clair (2002)	15	Observational, quasi-experimental single group	Weekly 40 min, 6 weeks	Group	Administration staff provided brief written description of study to legal representatives	Admin staff			73%	46%	Proxy consent (family or close friend caregiver)
Clair et al. (2005)	45	Observational, quasi-experimental single group	Weekly, 15 min, 8 weeks	Group	Leisure activity staff contacted legal guardians by phone or face to face	Leisure staff			NR	0	Written proxy consent (guardian) after activity director described the study verbally and provided them with consent documents. Implicit participant assent (voluntary attended music session after invitation to the study)
Clements-Cortes (2015)	28	Single group, mixed methods, quasi-experimental	Weekly, 60 min, 16 weeks	Group	Verbally conveyed by staff and presented in flyers	Care home staff and leisure staff			NR	0	Written and verbal self-consent or proxy consent (substitute decision maker) + participant assent after receiving information sheet
Guétin et al. (2009)	30 (target 30)	RCT, parallel group	Weekly, 20 min, 16 weeks	Individual	Selected by staff		10	2.8	79%	40%	Written self-consent or proxy consent (family or legal representative) at the end of inclusion visit, after patient information
Ho et al. (2011)	31	Quasi-experimental, single group	60 mins, 2× per day, 4 weeks	Group			5.1	6	74%	4%	Written self-consent and proxy consent (cosigned by family member)
Hsu et al. (2015)	17	Cluster RCT feasibility	Weekly, 30 min, 5 months	Individual	Selected based on staff referral		8.5	2	100%	42.50%	Proxy consent for residents (next of kin), self-consent for carers
Ledger and Baker (2006)	45	Cluster, nonrandomized	Weekly, 45 min, 12 months	Group					91%	27.5%	Consent obtained for all participants

Recruitment Strategies in Music Therapy

Publication	Study		Intervention		Recruitment Details						
Author (Year)	Sample Size	Design	Length	Type	Strategies	Recruiter	Rate per Month	Period (Months)	Conversion of Eligible to Enrolled	Attrition Rate	Consent Details
		controlled trial, parallel group									
Ray and Götell (2018)	62 (target 70)	Quasi-experimental, single group	3× week, 30–60 min, 2 weeks	Group	Referrals staff	Nurses, social workers, leisure			NR	11%	Written proxy consent (legal representative) and verbal participant assent
Ray and Mittelman (2017)	132	Quasi-experimental, single group	3× week, 15–60 min, 2 weeks	Group	Referrals staff	Nurses, social workers, leisure			NR	7%	Written proxy consent (legal representative) and verbal participant assent
Ridder et al. (2013)	42	RCT, crossover	Weekly, ~30 min, 6 weeks	Individual			21	2	93%	17%	Written proxy consent (relative) or self-consent
Svansdottir and Snaedal (2006)	38	RCT, case controlled	3× week, 30 min, 18 weeks	Group					98%	20%	Written proxy consent (close relative)
Werner et al. (2017)	117	Cluster RCT	2× week, 40 min, 11 weeks	Group	Researchers explained study to residents and then obtained consent				100%	3%	Written self-consent or proxy consent (legal guardian)
Mean	52.43 (37.8)						12.62 (6.8)	2.93 (1.8)	89% (0.11)	16% (0.17)	

Note. NR = not reported; RACF = residential aged care facility; RCT = randomized controlled trial. All studies were conducted with people living with dementia.

Table 3 – Recruitment Characteristics of Music Therapy Studies Delivered in Community Settings

Publication	Study Details		Intervention Details		Recruitment Details						
Author (Year)	Sample Size	Study Design	Length	Type	Strategies	Recruiter Details	Rate per Month	Period (months)	Conversion of Eligible to Enrolled	Attrition Rate	Consent Details
Baker et al. (2012)	5 dyads	Quasi-experimental, single group	3× weekly, 6 weeks	Individual	Information sessions at support groups, advertisements, articles in aging-related newspapers, referral from community workers	Researchers			NR	NR	Self-consent
Baker et al. (2018)	14 carers	Mixed methods, nonrandomized, single group	Weekly, 60 min, 6 weeks	Group	Contacted carers by phone or in person to invite them prior to providing written PLS and obtaining consent	Day center manager	14	1	48%	0	Written self-consent
Berger et al. (2004)	36	Quasi-experimental, two group, matched controls	Weekly, 45 min, 8 weeks	Group	Recruitment on admission to clinic	NR	3	12	NR	33% at 12 months, 58% at 24 months	NR
Choi et al. (2009)	20	Pilot RCT	3× weekly, 50 min, 5 weeks	Group	Advertised study at site	NR			91%	0	Written self-consent after they and their caregivers were explained the intervention, nature of dementia, and study procedures
Clements-Cortes (2013)	28	Single group, mixed methods, quasi-experimental	Weekly, 60 min, 16 weeks	Group	On-site presentation of study to potential participants. Flyers disseminated by post. Staff referral of interested people	Researchers and staff			NR	0	Written self-consent or proxy consent (substitute decision maker) + participant assent after verbal explanation and receiving letter (consent to participate or assent to participate)
de la Rubia Orti et al. (2018)	25	Quasi-experimental, single group	60 min, single session	Group	Staff corresponded with legal representatives	Neurologist			NR	NR	Proxy consent (legal guardians)
Garcia-Valverde et al. (2020)	31	Quasi-experiment, single group with repeated measures, pre-post	Weekly, 60 min, 12 weeks	Group	Newsletter sent to potential participants on Dementia Association database. Interested participants contacted researchers by phone	NR			53%	32%	Written self-consent

Recruitment Strategies in Music Therapy

Publication	Study Details		Intervention Details		Recruitment Details						
Author (Year)	Sample Size	Study Design	Length	Type	Strategies	Recruiter Details	Rate per Month	Period (months)	Conversion of Eligible to Enrolled	Attrition Rate	Consent Details
Giovagnoli et al. (2018)	45	RCT, parallel group	2× weekly, 40 min, 24 weeks	Group	Former hospital patients contacted by phone and informed about the trial	NR	5.6	8	72%	0	Written self-consent
Han et al. (2010)	45	Quasi-experiment, single group	Weekly, 45 min, 8 weeks	Group	Selected by staff clinic	Clinic staff			71%	4%	Proxy consent (family caregiver or legal representative)
Hanser et al. (2011)	14	Single group, multiple baseline	2-hr, single session	Individual	Selected by staff from people attending community clinic	NR			100%	57%	Written self-consent
Holden et al. (2019)	18	Quasi-experiment, single group, feasibility	Weekly, 60 min, 6 weeks	Individual	Selected by staff from people attending community clinic	NR	1.3	14	NR	50%	Written self-consent or proxy consent (caregiver) + participant verbal assent
Ihara et al. (2019)	51	Nonrandomized controlled trial, parallel group	2× week, 20 min, 6 weeks	Individual	Potential participants identified and contacted by staff. Consent sought by researchers	Care staff, researchers			NR	9.4%	Self-consent and proxy consent (legal representative)
Mittelman and Papayannopoulou (2018)	11 dyads	Quasi-experimental, single group, mixed methods	Weekly, 120 min, 13 weeks	Group	Informed about study at Carer support groups	NR			NR	9%	NR
Sarkamo et al. (2014)	89 dyads	RCT	3× week, 50 min, 12 weeks	Group	NR	NR	3.7	24	NR	17%	Written self-consent
Schall et al. (2015)	14	Quasi-experimental, time-series	Weekly, 23–39 min, 6 months	Individual	Newspaper advertisements and referral from Dementia Association	NR			NR	36%	NR
Tamplin et al. (2018)	12 dyads	Quasi-experimental, single group	Weekly, 120 min, 20 weeks	Group	Potential participants invited to info session by dementia community services organizations. Information sessions, distribution of flyers to community dementia groups with invitations by researchers	Researchers	3	4	60%	25%	Written self-consent
Mean	28.62 (21.2)						5.1 (4.2)	10.5 (7.5)	71% (18)	2.7 (8.7)	

Note. NR = not reported; PLS = plain language statement; RCT = randomized controlled trial. Dyads indicate that there was both a carer and a person living with dementia. If not otherwise stated, sample size was with people living with dementia only.