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General discussion
General discussion

Introduction

The main goal of this thesis was to study the effects of a home-based physical exercise and support intervention on the functioning and health of people with dementia living in the community and on the psychological distress of their informal caregivers. This intervention is based on an adapted and elaborated version of an intervention developed by Linda Teri et al. (2003) in the US. From an efficiency point of view, it is worthwhile to translate a promising intervention programme already developed and found to be effective in another country. Furthermore, this intervention seems to have potential for the improvement of caregivers’ health as well. This has not been studied yet, but would be worthwhile to do, because earlier research has found that pleasant activities and physical exercises may also reduce caregivers’ psychological distress.1,2 The effects of physical exercise on the cognitive functioning of people with dementia living in the community, may also be worthwhile regarding the results of earlier results.3,4

To adapt the US intervention to the Dutch culture we made use of a stepwise approach. Firstly, the original intervention of Teri et al. (2003) has been literally translated into Dutch. Secondly, we conducted a small pilot study to evaluate its feasibility and the time needed for its provision. In a third step we excluded one of the treatment components, namely cognitive reframing, to shorten the intervention (chapter 4). In addition, we decreased the number of home visits to eight instead of the original twelve in order to comply with Dutch health insurance regulations about the number of care sessions that would be reimbursed, and to reduce the burden for the participating dyads. In the final step, we revised and expanded the training manuals for the dyads as well as for the coaches. All coaches followed a training programme on geropsychology and an extensive training to provide the home-based physical exercise and support intervention. To ensure that all coaches followed the adapted original intervention protocol in the same way, they received supervision from a psychologist (Anna-Eva Prick).

This thesis describes the results of a qualitative study concerning a process evaluation and a quantitative study concerning a Randomised Controlled Trial (RCT) of a home-based physical exercise and support intervention. The results of the process evaluation were determined by using a mixed-method design combining qualitative and quantitative data. For the RCT, a total of 111 people with dementia and their informal caregivers (dyads) living in the community were randomly allocated to the intervention group (n=57) or to the comparison group receiving a minimal intervention (n=54). The outcomes were measured at baseline, 3 months (post measurement) and 6 months. The effects of the RCT were determined by using generalised estimating equations (GEE) based on an intention-to-treat analysis.

In the RCT, a home-based physical exercise and support intervention was compared...
with a minimal intervention.

The physical exercise component in the experimental condition consisted of flexibility, strengthening, balance and endurance exercises. The support component consisted of psycho-education, communication skills training and a training to organize pleasant activities. A personal coach visited the dyads in their own homes for eight 1-hour sessions to teach and practice exercises and provide support. Alongside these home-visits, dyads received homework to practice physical exercise and to plan pleasant activities. The comparison group received a minimal intervention consisting of monthly written information bulletins and monthly maximum ten-minute phone calls.

It was expected that this multicomponent dyadic intervention would enhance the functioning and health of the person living with dementia and the psychological distress of the informal caregiver by involving both of them in the intervention.

The study design and the experimental and minimal intervention are described in more detail in chapter 3.

This general discussion summarises the main findings of this thesis per research question followed by a reflection on the findings. We subsequently discuss several general methodological issues, recommendations for further research and the implications of the outcomes for clinical practice and care policy.

Summary of the main findings

The results presented in this thesis provide answers to the following four research questions (see also chapter 1):

1. What are the effects of dyadic psychosocial interventions on functioning and health of people living with dementia in the community and on psychological distress of their informal caregivers in previous research?

In chapter 2, we reviewed the effects of dyadic psychosocial interventions for people with dementia living in the community and their informal caregivers. The study updated a previous review which included publications up to 2005. The authors found that psychosocial interventions may contribute to the quality of life of both members of the dyad and may decrease caregivers’ mental health problems. In our update of this systematic review, we concluded that dyadic psychosocial programmes are effective, but the outcomes for the person with dementia and the caregiver vary. In addition, compared with the previous review, we could be more specific: psychosocial interventions with components which were related to the targeted functional domains were promising, adding to a better quality of life for both the person with dementia and the caregiver. This was the case especially for the outcomes ‘activity and functional dependence’ of the person with dementia and ‘competence’ of the caregiver. The effects on other outcomes were more heterogeneous, and the relationships with the treatment components or delivery characteristics were less clear-cut. The increasing number of
moderate to good quality trials of psychological and psychosocial interventions for people with dementia and their informal caregivers is encouraging. In future research more attention is needed for matching the targeted functional domains, intervention components and delivery characteristics of a programme with the needs of the person with dementia and the family caregiver.

2. What is the quality of the execution of our study and what is the feasibility of a home-based physical exercise and support intervention?

Through a process evaluation (chapter 4) we created insight in: (a) the quality of the success rate of recruitment and the quality of the study population; (b) the quality of the execution of the intervention and the experiences of the participants with the intervention, and; (c) the quality of the data collection process. We evaluated these process components according to a structured framework especially designed to evaluate complex interventions. To assess each process component we made use of a mixed-method design, combining qualitative and quantitative data-analysis.

Ad a) Evaluation of the way in which the study was conducted revealed a profound recruitment process resulting in a reasonable sample size. It was difficult to find interested dyads and, therefore, the recruitment process took longer than originally planned. What did work was a personal approach of the dyads by visiting local Alzheimer cafes and personally contacting potential participants and their case managers. In total, 111 dyads living throughout the Netherlands met all the eligibility criteria. However, the recruitment efforts may have generated a self-selected group of dyads who were very motivated to exercise and not those who did not like physical exercise or were not familiar with physical exercise. Self-evidently, this could have influenced the external validity. By selecting this relative active group of dyads, it might be that there is not enough room for improvement to measure effects. In total 23 dyads (21%) dropped out which is a reasonable dropout rate. Conventionally, a 30% dropout rate is regarded as acceptable in this older population dealing with the degenerative dementia process.

Ad b) In total, 44 dyads (77%) completed all eight home visits together with the coach. This number indicates that it was feasible to deliver the intervention at its current frequency and duration. During the home visits by the coach, all the dyads were willing to participate in all the intervention components. Meanwhile, in the absence of the coach, the dyads differed in performing their exercise and pleasant activities homework. In the intervention group, 39 dyads (69%) continued to perform physical exercise at home and 27 dyads (47%) continued to plan pleasant activities on their own. This indicated that performing physical exercises might be better suited to the needs of the participants than planning pleasant activities. As a consequence, we concluded that the results of the RCT (chapter 5, 6 and 7) should be interpreted with caution, due to the limited extent to which homework (physical exercises and planning pleasant activities) was performed.
To explore the experiences of the participants, we used data from semi-structured interviews with eleven dyads that completed the eight home visits of the intervention. Most of the interviewed people with dementia and informal caregivers experienced benefits from both the physical exercise and the support component of the intervention. Regarding the exercise intervention component most people with dementia and almost all caregivers reported improved pleasure and mood. Some people with dementia and a few caregivers indicated improved self-esteem. Some people with dementia and almost all caregivers mentioned increased awareness of the importance to exercise and some caregivers experienced doing exercises as a pleasant daytime activity. In addition, an interesting mutually benefit of the exercise component was improvement of the quality of relationship as mentioned by about half of the caregivers and some people with dementia. Regarding the support component of the intervention, most caregivers indicated that a general benefit of the conversations with the coach was decreased loneliness. Thinking about pleasant activities made most caregivers more aware of the importance of these activities.

All interviewed dyads indicated that different intervention components contributed to their experiences. Both the people with dementia and the caregivers were positive about the encouraging support of the coach. Almost all caregivers indicated that the support of the coach had more impact on the person with dementia than their own support. The use of a ball during some physical exercises functioned as a booster to enhance interaction and pleasure between the person with dementia and the informal caregiver. The pictures in the user manual functioned as an important non-verbal communication tool for people with dementia to perform their physical exercise homework. The use of the pleasant activities logs, in which they planned and wrote down their pleasant activities, worked out as a mnemonic and motivator for the caregivers. On the negative side, a few caregivers mentioned that doing some exercises, in particular strengthening and balance exercises, confronted the person with dementia with physical and mental inabilities. In addition, a few caregivers experienced performing the intervention to be a burden because of losing too much of their valuable time.

Ad c) Evaluation of the data acquisition showed a careful collection of data with almost no missing data. In all people with dementia (n=111) and almost all the caregivers (n=110) there were no missing values on the primary outcomes in all the measurements other than due to dropout. Furthermore, the evaluation of the data acquisition showed the positive value of the use of a mixed design: qualitative analysis of interviews with eleven dyads suggested benefits not measured in the quantitative analysis.
3. What are the effects of a home-based physical exercise and support intervention on the functioning and health of people with dementia living in the community?

Regarding the people with dementia, effect analysis showed a small significant effect of the intervention on an attention task when adjusting for possible confounders and baseline outcomes (chapter 6). No effects of the home-based exercise and support intervention were found on memory, executive functioning (EF), depressive symptoms, physical health and behaviour outcomes of people with dementia (chapter 5 and 6).

4. What are the effects of a home-based physical exercise and support intervention on the psychological distress of informal caregivers who care for people with dementia living in the community?

The effect analysis of the RCT showed no effects of the home-based exercise and support intervention on depressive symptoms, burden, general health and salivary cortisol levels of caregivers (chapter 7).

Reflection on the findings

In this paragraph, we reflect on the relevance of the findings of this thesis in relation with the results of Teri et al. (2003) and the recent literature.

Explanations for finding hardly any results

The process evaluation (chapter 4) demonstrated a carefully and soundly performed study. Most interviewed participants experienced benefits of the intervention on other outcomes than measured in the quantitative analysis. The quantitative results of our RCT study are not in line with the benefits on physical health and mood in people with dementia found in the study of Teri et al. (2003). Our RCT showed only a small significant effect of the intervention on an attention task for people with dementia (chapter 6). No quantitative effects of the intervention were found on other indicators of the functioning of people with dementia or caregivers’ psychological distress (chapter 7).

There might be different explanations for finding hardly any effect of this intervention.

- Adaptation of the intervention

A first reason might be that we adapted the intervention in a way that made the intervention ineffective. We excluded the cognitive reframing component which was part of the original intervention. We know from the literature, that cognitive reframing is an effective strategy to reduce depression and behavioural problems.\(^8\)\(^{-10}\) The choice to drop cognitive reframing was motivated by the fact that meanwhile there is an important database suggesting that cognitive reframing is effective,\(^8\) whereas the effectiveness of physical exercise and pleasant activities training for people with dementia living in the community and their informal caregivers was less well studied. In addition, the
evaluation of the pilot study showed that a proper execution of an initial version of the intervention took more than one hour. That was an additional reason to mainly concentrate on physical exercise and the pleasant activities training. Thus, it might be that cognitive reframing was the active intervention component in the original intervention studied by Teri et al. (2003).

- **Homework not performed as prescribed**
  Secondly, physical exercise homework was not performed as frequently as prescribed: 30 minutes of active exercise at least three days a week. However, improving physical health with physical exercise might be only effective if the physical exercises are of moderate-to-high intensity. A dose-response relationship has been suggested in healthy older people showing that higher levels of physical activity are associated with better cognitive performance.\(^{11}\) In addition physical activity has an association with the volume of the prefrontal and hippocampal brain areas, which are mainly affected by dementia.\(^{12-14}\) The authors of a review published after the start of our intervention, found the largest improvements on physical functioning and activities of daily life performance of people with dementia, in interventions with the largest training volume: interventions with a minimum of 12 weeks, a frequency of three times a week and 45–60-minute sessions.\(^{15}\)

- **Burden of the intervention**
  Thirdly, intensive usual care usage of the participants might have caused feelings of burden by also participating in our intensive intervention alongside the usual received care (chapter 4). The authors of a report studying the Dutch dementia care situation found that 18% of the 554 participants received one or more days respite care in a day care facility where people with dementia participate in many active activities.\(^{16}\) The number of people with dementia included in our trial receiving respite care in a day care facility was even higher: 50%. Informal caregivers who participated in our trial also received case management (35%), they participated in support groups (14%), visited Alzheimer cafes (37%) and/or made use of a buddy at home (8%). In total 47% of all informal caregivers made use of one or more of these types of care.

- **Selected group of dyads**
  Fourthly, recruitment efforts may have generated a self-selected group of dyads that was more active. In the present research project, as described in chapter 4, recruitment was time consuming and complicated in this population. During the recruitment process we had to change our strategy. Our starting strategy, recruiting via advertisements in national and local newspapers and on information websites for people with dementia and their caregivers yielded almost no reaction from potential interested dyads. Changing our recruitment strategy, by shifting towards a more personal approach via presentations at Alzheimer cafes and by personally contacting case managers,
was much more successful in recruiting dyads. The possibility to exercise during the intervention was the most named reason by the interested dyads to participate in the study. However, the participating dyads were ‘already’ active and familiar with physical exercise: 78% of the dyads referred to our intervention were already physical active at the start of the intervention (chapter 4). Our recruitment strategy could have influenced external validity by not approaching dyads that did not like physical exercise or were not familiar with physical exercise. In addition, by selecting this relative active group of dyads, it might be that there was not enough room for improvement to measure the effects on the present measured outcomes. Although the physical exercise component of the intervention was in line with the participants’ preferences, it raises the question whether there is a need for active dyads to join an active intervention. This issue reveals some tension between the preferences and necessary needs of a target population and should be well considered in future research.

Methodological issues
Although the study was carried out in an appropriate way, there are some methodological issues which might have had an impact on the results found. These issues are described in this section.

STUDY POPULATION
Some issues which should be acknowledged for proper interpretation are related to the study population. A first issue regarding the study population is that the sample size in the RCT study was smaller than intended according to the power calculation: 111 dyads instead of 156 dyads were randomised. In the field of this type of research, the present sample size is still reasonable. However, even with a larger sample of 156, we would not have found significant results. The outcomes score for the baseline and post-measurements showed hardly any difference at all. Even worse: depression scores in both people with dementia and their informal caregivers and behavioural problems scores in people with dementia significantly increased in the experimental group.

Another study population issue concerns attrition. The loss to follow-up (<30%) was reasonable for long-term follow-up studies, but concerned the most vulnerable participants due to the mortality of the person with dementia, nursing home placement or hospitalisation, or health problems, or because the study was perceived as being too much of a physical or mental burden. Dropout in caregivers was mainly due to too much perceived burden of the study in combination with providing care. For both the intervention group and the comparison group the dropout rates were comparable. Unfortunately, loss to follow-up is inherent in this type of intervention studies: it is difficult to recruit and retain such a vulnerable group in research. However, by carrying out an intention-to-treat analysis in which all participants are analyzed according to the initial randomization scheme, we avoided the effects of dropouts, which could break the random assignment to the intervention or the comparison group.
BLINDING
Possible difficulties with blinding should also be acknowledged for a proper interpretation of the results. The general view is that inappropriate control conditions can overestimate the effectiveness of a treatment, or frustrate a potentially useful treatment. With psychological interventions, unlike drug trials, there is a fundamental problem regarding the blinding of client and coaches.\textsuperscript{18,19} In the present RCT study, as in other psychosocial intervention studies, we could not carry out a double blind study because the people with dementia and their informal caregivers knew whether they received the intervention. We tried to blind the research-assistants and asked the dyads not to inform them about which type of intervention they received. However, in practice group allocation often became clear to the research-assistants. Since we found hardly no beneficial impact of the intervention, and even negative effects for the intervention group, the lack of blinding is not an issue for the outcomes of this study.

‘REDUCING HEALTH PROBLEMS’ VERSUS ‘POSITIVE OUTCOMES’
This study was focused on reducing physical and mental health problems, and not on the improvement of relationships or quality of life. The findings in chapter 4 and 7 showed that caregivers report feelings of satisfaction and pleasure of the received dyadic intervention. However, the quantitative measurements showed that depression scores appear to rise over time in the treatment group in both people with dementia and their informal caregivers. These perceived benefits (increased pleasure, increased relationship quality, increased self-esteem, decreased loneliness, better awareness of the importance of pleasant activities and doing exercises as a new daytime activity in case of bad weather) were not the focus of this study and therefore not included in the RCT. These benefits might be a consequence of the adaptations to the original intervention of Teri et al. (2003) we made. We stimulated to identify joined activities which were pleasant for both members of the dyad alongside identifying pleasant activities for the members of the dyad apart and we added different duo exercises to the physical exercise protocol to stimulate contact and pleasure. For example, the use of the ball resulted in interaction and increased pleasure. In addition, in spite of the absence of evidence of a beneficial effect of psychosocial interventions on caregivers’ distress, caregivers generally reported feelings of satisfaction about the received intervention like has been found for other interventions such as caregiver support groups.\textsuperscript{21,22}

In 2007, after we had designed the present study, a European consensus on the outcome measures for psychosocial intervention research in dementia care is formulated:\textsuperscript{23} if rehabilitative goals are set to build on strengths and enhance positive capacity in the participants, then measures of positive capacity and positive aspects of care are needed. Because we changed the intervention increasing the dyadic focus, and adjusting the intervention in adding pleasurable components, this intervention might be helpful to improve those positive outcomes, regarding the results of the qualitative
MEASURING COGNITIVE FUNCTIONING IN PEOPLE WITH DEMENTIA

Other issues, which should be acknowledged for a proper interpretation of the results described in chapter 6, are related to the used neuropsychological tests to measure cognitive functioning in people with dementia. As described in the protocol (chapter 3), to assess the aspects of cognitive functioning (memory, executive functioning (EF) and attention) different neuropsychological tests were administered.

In practice part B of the Trailmaking Test was difficult to successfully administer: some people with dementia had difficulties in comprehending the test instructions causing missing and unreliable data and thereby less feasible.\textsuperscript{25} This test makes a specific appeal to mental flexibility, which is an important executive function, that is affected in dementia. Causing too much missing and unreliable data made us decide to leave this test out of the analyses (chapter 6). The authors of other comparable studies have also excluded neuropsychological tests of their final analyses because of similar problems.\textsuperscript{26-28} However, even with this test included, we would not have expected significant effects: we found no benefits of physical exercise on the EF domain with other EF tests (the \textit{Digit Span Test Backward} part of the Wechsler Memory Scale–Revised, the \textit{Key Search Test} of the Behavioural Assessment of the Dysexecutive Syndrome and the \textit{Category Fluency} which is a subtest from the Groninger Intelligence Test).\textsuperscript{29-31}

Recommendations for future research

Some implications for future research can be derived from this thesis.

• Importance of mixed methods design
We would like to stress the importance of a mixed method design when conducting an effectiveness study on psychosocial interventions. Information gathered through qualitative methods, in addition to the quantitative data of a RCT, contributes to valuable insights for the implementation of an intervention. Qualitative research can assist in understanding the meaning and active mechanisms of an intervention to clients as well as clients’ beliefs about the treatment and expectations of the outcome.\textsuperscript{32} It also helps in understanding the impact of the context and the process of the intervention. Finally, qualitative research is helpful in developing appropriate outcome measures for psychosocial interventions, for example the attention for ‘positive outcome’ measures as discussed earlier. These findings are in line with a recent review, aimed at exploring what existing qualitative studies reveal about the implementation, effects and processes of psychosocial interventions for dementia.\textsuperscript{33}

• Matching the needs for an improvement in functional ability and well-being
An interesting discussion point raised by the present study is when psychosocial interventions for people with dementia and their caregivers fit their needs. In chapter
2, we concluded: “Since a clinician has to determine which program works for which dyad, matching the goals of a program with the needs of both members of the dyad is necessary to support them in their daily lives. Reflection on the results during the program is also necessary, and adaptation or a change to other support programs may be required”. However, our findings show that matching an intervention to the needs of the participants is something else than matching an intervention to their preferences. It might make more sense to let people participate in an intervention that they might not prefer, but improve their functional ability. For example, our home-based physical exercise and support intervention might have a beneficial impact on people with dementia and caregivers who are rarely or not at all involved in physical exercise. As described by the World Health Organization, for healthy ageing, a process of developing and maintaining the functional ability that enables well-being in older age, is necessary. To maintain or increase a level of functional ability it is sometimes necessary to conduct activities that are not perceived as pleasant in the first place, like physical exercise for some people or performing homework assignments.

Implications for clinical practice and policy
Some implications for clinical practice and policy can be derived from this thesis.

• Involve case managers as important informant from the start of the study process
  We argue for involving case managers as an important informant from the start of the study process and to increase the numbers of participants, as was the case in this study. Case managers provide practical, emotional and social support and know the personal situation of the dyad well. The experiences and knowledge of case managers will increase the recruitment success and might be worthy in matching an intervention with participants’ needs. The strength of case managers is that they personally guide the person with dementia and their informal caregiver through the whole complex process of care as long as required. Since the key role for coordinating care for people with dementia and their caregivers, case managers are an excellent starting point for psychosocial interventions. It is important when they are enabled to play this important role in research.

• Critical reflection on the active involvement of caregivers in dyadic interventions
  Informal caregivers are crucial in the success of the implementation of home-based psychosocial interventions such as the home-based exercise and support intervention described in this thesis. However, critical reflection of the burden-benefit ratio regarding the role of family members as an active in dyadic interventions is required. Researchers and also clinical practitioners and policymakers must ask themselves whether they are at the right track to stimulate such a role without taking the burden of caregivers into account.
  In the present research project, informal caregivers mentioned difficulties in motivating
the person with dementia in performing the exercises and became demotivated in performing the intervention themselves (chapter 4). Informal caregivers indicated that the remarks of the coach had more influence on the person with dementia than their own remarks in the absence of the coach (chapter 4). Caregivers also mentioned that there was a continuous desire and need for involvement and encouragement from the coaches to help the dyads with their homework exercises instead of performing the exercises on their own. Difficulties with homework assignments in a frail target population are inherent in working with this frail population.\textsuperscript{37,38}

For future research and clinical practice, to protect the informal caregiver against burden, it is important to make the informal caregiver less responsible for the training of the person with dementia during a dyadic intervention by anchoring continuous professional (blended) coaching. Only sticking to face-to-face meetings between a professional coach and dyad is expensive as well as a burden to the free time left of the informal caregiver. The use of blended care (combination of coaching via mobile phone, online chat and face to face meetings) could be both cost-effective and time-saving. Earlier studies demonstrated the benefits of online interventions (e-health) and ICT solutions such as telecoaching and videoreminders for people with dementia and their informal caregivers.\textsuperscript{39-42} It would be helpful to develop blended coach manuals and online tools for home based exercise interventions, which make it possible to consult between coach and dyad on a more frequent and payable basis to enhance exercise performance.

In addition, when implementing a dyadic intervention, it is important to anchor appropriate individual support for the informal caregiver to prevent the caregiver from burden. This support needs to be planned without the presence of the person with dementia, so the caregiver feels not controlled by the person with dementia and can speak his or her thoughts and feelings out freely, as indicated in chapter 4. As mentioned hereinabove, this support can be provided online, like the iSupport intervention under development by the World Health Organization.\textsuperscript{35} Using problem solving techniques can be very helpful during this support: problem-solving techniques focus on ensuring that caregivers understand how cognitive limitations can impact the understanding of a person with dementia and their cooperation with an intervention component like physical exercise. Adequate support can help caregivers to learn how to use communicative and behavioural strategies effectively, to guide and motivate the person with dementia and to protect themselves against burden.

\begin{itemize}
\item\textbf{Enhancing the motivation of people with dementia to exercise}
\end{itemize}

It is important to think carefully about the possibilities to enhance the engagement of people with dementia in a dyadic intervention, especially when the informal caregiver is made less responsible for the training of the person with dementia during a dyadic intervention. Different strategies can be used to enhance the engagement of people with dementia. In case of motivational problems, the question arises how motivation
in people with dementia can be enhanced (chapters 4 and 6).

The use of music or video during the exercise training was a frequently heard wish of the participants and, therefore, music or video accompanying the physical exercises might increase levels of participation in exercise. Other ways presented to increase engagement are to match exercises to meaningful activities, to adapt the time of exercising based on diurnal fluctuations, and the use of descriptive prompts and appropriate cueing to meet the person’s needs. A recent systematic review presented different ways of modifying activities to enhance engagement in physical activities.\textsuperscript{43}

For future research and clinical practice, we recommend including possible strategies to enhance motivation in people with dementia in the intervention protocol, before the start of the intervention.

- Development of flexible personalised dyadic interventions to address the needs and preferences of the people with dementia and their informal caregivers

In line with the recent literature, the present research project underlines the need for flexible personalised care in dementia.\textsuperscript{44} Organising and supporting psychosocial care for people living with dementia in the community and their informal caregivers means dealing with a complex interaction of personal needs and limitations, coping styles, problem awareness, actual usual care and their social network. Rothera et al. (2008) found that the most effective forms of home care with the best outcomes are flexible in their design and responsive in their delivery.\textsuperscript{45} The findings in chapters 2 and 4-7, show that not every intervention component fits well to all people with dementia and their informal caregivers. Although our design was partly flexible in adapting intervention components better to the (changing) needs of the participants (for example adapting the intensity and type of physical exercises), a more anchored flexible design would have been helpful. If we had anchored more flexibility in our protocol, we might have been better able to react to the changing needs of the participants. For example, some informal caregivers mentioned their needs for more private time with the coach without the person with dementia being present or expressed feelings of loneliness (chapter 4). These experiences and needs are in line with the results of another qualitative study into the experiences of caregivers who were attending a multicomponent psychosocial intervention programme for caregivers and people with dementia.\textsuperscript{46} In this study some caregivers expressed their needs for extended content like information to be given about financial matters, feelings of loneliness and guilt and the need for group organisation. It would be helpful if it is allowed according protocol to be able to meet these needs.

All these findings indicate that it is important to match the intervention components, and delivery characteristics of a programme with the (changing) needs and characteristics of the person with dementia and the informal caregiver. For future personalised dyadic dementia care, it is crucial to anchor these flexibilities in the manual of an intervention and to monitor the personal needs of the dyads during an intervention to adjust an intervention when needs and preferences change during the course of the disease.
## Table 1. Summary of recommendations for clinical research, practice and policy

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<th>Classification</th>
<th>Recommendations</th>
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| **Methodological issues** | - Make use of ‘positive outcome instruments’ such as measuring pleasure, self-efficacy, mastery and coping alongside measuring negative feelings.  
- Make use of a mixed design to enable interpretation of outcomes. In addition, a mixed design contributes to valuable insights for the implementation of an intervention gained from the integration and interpretation of qualitative and quantitative data.  
- Perform a process evaluation of the study and the intervention when conducting complex intervention research.  
- Match the needs for an improvement in functional ability and well-being. It might make more sense to let people participate in an intervention that they might not prefer, but improve their functional ability. To maintain or increase a level of functional ability it is sometimes necessary to conduct activities that are not perceived as pleasant in the first place, like physical exercise for some people or performing homework assignments. |
| **Practical issues**     | - Involve case managers as important informants from the start of the study process and to increase the numbers of participants. The experiences and knowledge of case managers will increase the recruitment success and might be worthy in matching an intervention with participants’ needs.  
- Protect the informal caregiver against (extra) burden: make the informal caregiver less responsible for the training of the person with dementia during a dyadic intervention by anchoring continuous professional coaching and anchor appropriate individual support for the informal caregiver. This support can be provided online.  
- Increase the engagement of people with dementia in a dyadic physical exercise intervention. Include a strategy to enhance motivation in people with dementia to improve their active engagement from the start of the study. Possible strategies to enhance motivation are the use of music or video, matching exercises to meaningful activities, the use of descriptive prompts (for example a specific description of an activity of interest to the person with dementia), appropriate cueing to meet the person’s needs (for example adding visual cues and tactile cues) and the time of day exercises are introduced should be based on diurnal fluctuations.  
- Match the intervention components, and delivery characteristics of a programme with the (changing) needs and characteristics of the person with dementia and the informal caregiver. Anchor these flexibilities in an intervention protocol and monitor the personal needs of the dyads during an intervention to adjust an intervention when needs and preferences change during the course of the disease. |
Conclusion
The current scientific literature emphasises the need for dyadic multicomponent psychosocial interventions to enable people with dementia to stay at home as long as possible. Up to now, few multicomponent psychosocial interventions which focus on both the person with dementia living in the community and the informal caregiver, have been studied. This thesis describes the results of a RCT of a physical exercise and support intervention in the community.

The results show no benefits over time on any of the outcomes for both people with dementia and their informal caregivers, besides a small effect on the attention of people with dementia. Qualitative data suggest that this intervention might be more suited to improve positive outcomes for the dyads such as increased experienced pleasure in joined activities, improved quality of the relationship between the person with dementia and the informal caregiver, and increased feelings of self-esteem as was mentioned by both people with dementia and their informal caregivers in the qualitative sub-study.

Further research needs to be conducted into flexible personalised dyadic home-based interventions to support the benefit of people with dementia, their caregivers and society as a whole. In 2016, the government policy is aimed at letting older people live at home as long as possible with large responsibilities for local authorities and citizens themselves. The burden on caregivers will be even higher by this shift from formal to informal care without additional support. Home-based psychosocial interventions should be well adjusted to the needs and burden-benefit ratio of dyads.

Although we did not find a beneficial impact of the intervention, this thesis adds to the discussion on the relevant developments to support people with dementia and their informal caregivers living at home to enhance their functional ability and well-being over time and enable them to live in dignity.


