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Chapter 1 is a general introduction to the Randomised Controlled Trial (RCT) described in this thesis, to improve the functioning and health of people with dementia and to reduce the psychological distress of their informal caregivers. Dementia is an increasing prevalent disease with a substantial impact on the individual level as well as on society as a whole. Most people with dementia are cared for at home and depend on care mostly provided by their spouse and/or their adult children. Those informal caregivers are confronted with serious psychological distress, like depression, as a result of the care for a person with dementia over a longer period of time. Effective support is needed to improve the functioning and health of people with dementia and to reduce the psychological distress of informal caregivers. Psychosocial dyadic interventions addressing both the person with dementia and the informal caregiver and multicomponent interventions are assumed to be effective. One component that receives growing attention is physical exercise especially for people with dementia. However, good quality RCTs are lacking.

The main aim 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 home-based physical exercise and support intervention was based on an adapted and elaborated version of an intervention developed by Linda Teri et al. (2003) showing significant results in the US. Although the effects on informal caregiver’s health were not studied in the study of Teri et al. (2003), the intervention might also have the potential to reduce caregivers’ psychological distress as has been found in earlier research. A secondary aim of this thesis is the evaluation of the quality of the execution of our study and determining the feasibility of the intervention.

Chapter 2 comprises a systematic review of the effects of dyadic multicomponent psychosocial interventions on psychosocial outcomes of people with dementia living in the community and their informal caregivers. The results showed that dyadic psychosocial programmes are effective, but the outcomes for the person with dementia and the caregiver vary. Psychosocial interventions with components which are related to the targeted functional domains are promising, especially for the outcomes of (I)ADL dependency of people with dementia and caregiver’s sense of competence, adding to better quality of life for both the person with dementia and the caregiver. The increasing number of moderate to good quality trials of psychological and psychosocial interventions for people with dementia and their informal caregivers is encouraging. However, in the future more attention is needed for matching the targeted functional domains, the intervention components, and the delivery characteristics of an intervention with the needs of the person with dementia and the family caregiver.
**Chapter 3** describes the design of the RCT in which we compared a home-based physical exercise and support intervention with a minimal intervention. Recruitment of participants took place via national and local newspapers, by giving presentations at Alzheimer cafes and personally contacting case managers. To be included in the study people with dementia needed a score of 14 or higher on the Mini Mental State Examination (MMSE) and their caregivers needed a score of 5 or higher on the Center of Epidemiological Studies–Depression scale (CES-D). Participants were block-randomised to one of the two conditions. The physical exercise component of the intervention consisted of flexibility, strengthening, balance and endurance exercises. The support component consisted of psycho-education, communication skills training and training to organize pleasant activities. A personal coach visited the dyads in their own homes for eight 1-hour sessions spread over three months 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 phone calls. Measurements were taken at baseline (pre-measurement) and at 3 months (post-measurement) and 6 months (follow-up measurement) after baseline. Primary outcomes were physical health and functioning (people with dementia) and mood (people with dementia and caregivers). Secondary outcomes were behaviour, cognitive functioning and actigraphy rest/activity cycles for people with dementia and general health, burden and adrenocortical activity for caregivers. Analyses were performed according to the intention to treat principle.

**Chapter 4** contains a process evaluation of the quality of the study and the home-based exercise and support programme for people with dementia living in the community and their informal caregivers. It provides information about the quality of the study population, the execution of both intervention components (exercise and support) and the experiences of the participants with these intervention components, and the quality of the data-collection process. After conducting the process evaluation, we concluded that the results of the statistical effect analysis should be interpreted with caution, accounting for the extent to which homework was performed and some negative experiences of participants, which may be an indication of a too intensive intervention for this frail and burdened population. At the same time, the results of the process evaluation demonstrated the pros of the present study project: namely a study design of high quality, an intervention protocol meeting high research standards, and valuable insights by using a mixed methods design. Adding qualitative data has given insight into active mechanisms of the intervention as well as both positive and negative experiences of the participants with the intervention. In summary, the results of this chapter show the importance of a process evaluation before effect analysis and the added value of a process evaluation in case of cross-country transmission of a complex intervention.
Chapter 5 describes the effects of the home-based physical exercise and support intervention on mood, behaviour and physical health of people with dementia. No effects of the home-based exercise and support intervention were found on mood (the Cornell Scale for Depression in Dementia, the Depression Rating Scale of the Resident Assessment Instrument Home Care and the Geriatric Depression Scale 15), physical health (the Medical Outcome Study 36-item Short-Form Health Survey and the Sickness Impact Profile) and behaviour (the Revised Memory and Behavior Problem Checklist) of people with dementia in both intention to treat and compliance analyses. In contrast, depression levels and behavioural problem scores significantly increased in the treatment group. The negative results might be explained by the translation and adaptation of the intervention used in the US, and a different social context. Furthermore, the results could be explained by experiencing the intervention too much as a burden and by the lack of room for improvement on the outcome measures by a too high entry activity level of the participants. In addition, improving physical health effectively might be only possible if the physical exercises are of moderate-to-high intensity and are tailored in accordance with the preferences and needs of the dyads.

Chapter 6 focuses on the effects of the home-based physical exercise and support intervention on the cognitive functioning of 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. No effects of the home-based exercise and support intervention were found on the memory and executive functioning (EF) of people with dementia in both intention to treat and compliance analyses. Finding only a small significant effect might be explained by moderate treatment adherence or a lack of room for improvement on the intended outcome measures because half of the people with dementia and their caregivers already received respite care in a day care facility.

Chapter 7 describes the effects of the home-based physical exercise and support intervention on the psychological distress of informal caregivers providing care to people with dementia. Effect analysis showed no effects of the home-based exercise and support intervention on mood (the Centre of Epidemic Studies-Depression), general health (self-rated general health), burden (the Self-Perceived Pressure from Informal Care and the Revised Memory and Behavior Problem Checklist) and adrenocortical activity (salivary cortisol) of informal caregivers providing care to people with dementia in both intention to treat and compliance analyses. In contrast, the depression scores appear to rise over time in the treatment group and general health scores significantly improved in favour of caregivers to the comparison group. These negative results are comparable with the analysed effects of the intervention on the outcomes of people with dementia (chapter 5). The possible explanation for these negative results might be explained by the translation and adaptation of the intervention that has been shown to be effective in the US. Furthermore, we hypothesised that the intervention was too
much of a burden for informal caregivers, which may be partly because caregivers in this study already received several other care services. In the US, the impact on informal caregivers has not been studied. Another discussion point is that measurements were directed at ‘negative’ outcomes (depression and psychological distress). ‘Positive’ outcomes like self-efficacy, mastery and coping might have shown a beneficial impact on other domains.

Chapter 8 is a general discussion summarizing the main findings of this thesis per research question followed by a reflection on the findings. We discussed different possible explanations for finding hardly any results of this intervention. In addition, we reflected on the relevance of the findings of this thesis in relation with the results of Teri et al. (2003) and the recent literature. The chapter ends with some implications for future research, clinical practice and policy, including the following recommendations:

- We recommend using a mixed methods design to enable the interpretation of outcomes and which contribute to valuable insights for the implementation of an intervention gained from the integration and interpretation of qualitative and quantitative data.
- Future research should 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.
- 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 intensive individual support for the informal caregiver. This support could be provided online.
- Increase the engagement of people with dementia in a dyadic physical exercise intervention. Include a strategy to enhance their motivation to improve their active engagement from the start of the study: describe in an intervention protocol possible strategies to enhance motivation.
- Match the components, and the delivery characteristics of an intervention 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.