# Efficacy of the ‘Cancer Home-Life Intervention’ in people with advanced cancer living at home:
# An occupation-focused and occupation-based intervention

PhD Dissertation

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2018

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## Acknowledgement

Ever since I did my bachelor, I have always wished to be involved in research in general and particularly in research that will strengthen the evidence-base of occupational therapy (OT) practice. In the present PhD project, I have had the honour not only to be involved in a research project investigating evidence of an OT intervention, but also shared time with people with advanced cancer for whom time is limited and very much valued. I have gained insights into how these people manage their daily life while living with an incurable disease where thoughts about 'life and death' are present and part of their daily life.

I would not have been able to complete this PhD project without having received support from many persons of whom I should like to single out a few to whom I am particularly grateful.

First and foremost, I wish to thank the 242 participants for having invited us inside their lives, sharing their thoughts at a very difficult time and for constributing with important knowledge.

I should also like to thank my supervisors, Åse Brandt, Karen la Cour and Anna Thit Johnsen for providing high-quality supervision, showing never-failing commitment and for always being straightforward, providing constructive and valuable critique when reading my work. You have taught me to be critical and to provide strong arguments for any decisions made. This has been immensely valuable to the present PhD project and will, undoubtedly, also be of much value to me in my future role as researcher.

I also wish to thank Lisa Gregersen Oestergaard who was part of the research group together with Åse Brandt, Karen la Cour and, of course, myself. You have always showed commitment and contributed with great knowledge of how to conduct randomised, control trials. Your knowledge has been very valuable to this study. The very fact that we managed to obtain the required sample size is in large measure owed to your effort to convince the heads of department to extend the inclusion period at Aarhus University Hospital (AUH).

I also wish to exspress my deepest gratitude to the staff at Odense University Hospital (OUH) and AUH for helping us including patients.

I should also like to thank and acknowledge the enormous commitment shown on the part of the occupational therapists from OUH and AUH who were involved in the intervention and the data collection. Particularly one occupational therapist made a big impression on me with her strong clinical knowledge and her fantastic commitment; Hanne Knudsen, we have spent many hours on the phone trying to coordinate the data collection, and you have even spent some of your holidays collecting data and talking with me. Thank you for having been such a very good colleague.

I also wish to thank my colleagues from the Research Initiative for Activity Studies and Occupational Therapy at University of Southern Denmark for reading my work and for supporting me during this PhD project. A special thanks to Eva Ejlersen Wæhrens and Kristina Tomra Nielsen for your continuous input to my work during the course of the study. Also a special thanks to Hanne Peoples and her husband for letting me stay at their appartment when I participated in various PhD courses in Copenhagen.

Lastly, I wish to thank my family for supporting and helping us looking after our children when I was occupied with late meetings and participated in conferences in different parts of the world; especially my father-in-law, Morten Pilegaard, who has been a kind mentor when I wrote this PhD project. I admire your great knowledge and your strong academic skills. Most important of all, I wish to express my deep gratitude to my children, Luis and Aya, and my wonderful wife, Britt, for reminding me about the true values of life; being with my family. I love you. My heartfelt appreciation goes to you, Britt, for always believing in me and supporting my work. Without you, I surely never would have completed this PhD project.

Financial support was kindly provided by the TrygFonden, the Danish Cancer Society, the University of Southern Denmark, the Danish Association of Occupational Therapists, and the Region of Southern Denmark.

## Preface

This study examines the efficacy of the 'Cancer Home-Life Intervention' for people with advanced cancer. The study is part of a larger research project, the **A**ctivity, **C**ancer, and **Q**uality of Life at Home project (ACQ project). The overall aim of the ACQ project was to develop and evaluate an occupational therapy programme that enables performance of and participation in everyday activities of people with advanced cancer living at home and hence increase their health-related quality of life (HRQoL). The ACQ project consisted of three studies: 1) a cross-sectional study identifying the problems and needs with everyday activities of people with advanced cancer; 2) a study on the development of an occupational therapy programme; and 3) a randomised controlled trial (RCT) examining the efficacy of the developed occupational therapy programme in people with advanced cancer living at home. I was involved in the third study of the ACQ project and had a minor role in the second study. As a member of the research group, I participated in the data collection, served as a study coordinator during February 2015 to December 2016, but was not involved in monitoring of the intervention delivery.

In the ACQ project, the term everyday activities was used to denote everything people do in their daily lives, like activities of daily living, work and leisure. Likewise, occupational therapy-based intervention was used to describe that the 'Cancer Home-Life Intervention' was based on principles from occupational therapy. The present PhD project is based on three papers using this terminology. The terms were coined since we wanted mainly to write for an interdisciplinary readership even if the present PhD project adopts an occupational therapy perspective. The reason for doing so is that I am an occupational therapist wherefore I will be using a conceptual framework that emanates from occupational therapy. This conceptual framework has been developed by Anne Fisher (1, 2) and so have the definitions of occupation and occupation-focused and occupation-based interventions as further discussed in the section on central definitions. Anne Fisher's framework was selected since it strongly emphasises the value of using occupation with regard to both intervention and evaluation (2).

The present PhD project evaluated the efficacy of the developed occupational therapy programme, the 'Cancer Home-Life Intervention', in three steps by first describing the evaluation plan, then performing the evaluation and finally exploring whether some subgroups of people with advanced cancer gained an effect. Efficacy and

cost-effectiveness were investigated by performing a full-scale, randomised, controlled trial (RCT). The economic analysis was not included in the present PhD project. If the 'Cancer Home-Life Intervention' shows to be efficacious, the next step is to implemented it in existing palliative care interventions.

January, 2018
Marc Sampedro Pilegaard

## Orginal papers in the PhD project

I. Brandt Å, **Pilegaard MS**, Oestergaard LG, Lindahl-Jacobsen L, Sørensen J, Johnsen AT, la Cour K. Effectiveness of the 'Cancer Home Life Intervention' on everyday activities and quality of life in people with advanced cancer living at home. A randomised controlled trial and a health economic evaluation: study protocol. BMC Palliative Care 2016; 15:10 DOI:10.1186/s12904-016-0084-9.

II. **Pilegaard MS**, la Cour K, Oestergaard LG, Johnsen AT, Lindahl-Jacobsen L, Højris I, Brandt Å. The 'Cancer Home-Life Intervention': A randomisered controlled trial evaluating an occupational therapy-based intervention in people with advanced cancer. Palliative Medicine; Article first published online: January 4, 2018 https://doi.org/10.1177/0269216317747199

III. **Pilegaard MS**, Oestergaard LG, la Cour K, Johnsen AT, Brandt Å. Subgroup effects of an occupational therapy-based intervention for people with advanced cancer. In review, Scandinavian Journal of Occupational Therapy.

The journals have approved that the publised articles (I and II) are reprinted in this PhD project.

## Definitions

***Central terms from Anne Fisher's conceptual framework:***

***Activity****:"The term activity pertains to the actions we observe (doing, task performance)"* (1).

***Activities of daily living (ADL)****:* Consist of Personal ADL (PADL) tasks related to self-care (eating, dressing and grooming) and Instrumental ADL (IADL) tasks related to home maintenance (cooking, shopping and housework) (3).

***Motor skills:*** Moving self or objects during observed occupational performance (3).

**O*ccupation****: "Being engaged in doing something that has meaning and/or purpose for the doer"* (1).

***Occupational performance:*** Performing a meaningsful and/or purposeful activity and unfolds as a dynamic interaction between the client, the task and the environment (1).

***Occupation-based:*** In occupation-based approaches, the client's occupational performance is observed during evaluation and practiced during intervention. More specifically, a client engages in occupation (2).

***Occupation-focused:*** When an occupation-focused approach is used, occupation is the immediate focus both in relation to evaluation and intervention, meaning that the OT and the client discuss his/her occupations and how to enable occupational performance by providing strategies to overcome the difficulties encountered (2).

***Process skills:*** Sequence of actions, select and appropriate use of tools and materials as well as adapt performance (3).

***Task***: *"What will be (or what was) done is the task"* (1).

## Abbreviations

| | |
|---|---|
| ADL | Activities of Daily Living |
| AMPS | Assessment of Motor and Process Skills |
| AUH | Aarhus University Hospital |
| CI | Confidence interval |
| CIOTS | Centre for Innovative OT Solutions |
| EORTC | European Organisation for Research and Treatment of Cancer |
| QLQ C-30 | Quality-of-Life Questionnaire Core-30 |
| HRQoL | Health-Related Quality of Life |
| IADL | Instrumental activities of daily living |
| IPAQ | Impact on Participation and Autonomy Questionnaire |
| IPA-DK | The Danish version of the Impact on Participation and Autonomy Questionnaire |
| IPPA | Individually Proritised Problem Assessment |
| OR | Odds ratio |
| OUH | Odense University Hospital |
| D-OT | Data-collection occupational therapist |
| I-OT | Intervention occupational therapist |
| OPEN | Odense Patient Data Explorative Network |
| OT | Occupational therapist |
| PADL | Personal activities of daily living |
| P-OT | Project occupational therapist |
| REDCap | Research Electronic Data Capture |
| RCT | Randomised controlled trial |
| SD | Standard deviation |
| T1 | Baseline |
| T2 | 6-week follow-up |
| T3 | 12-week follow-up |
| WHO PS | World Health Organisation Performance Status |

# Contents

## English summary

**Title:** Efficacy of the 'Cancer Home-Life Intervention' in people with advanced cancer living at home: an occupation-focused and occupation-based intervention.

This PhD project examines the efficacy of the 'Cancer Home-Life Intervention' for people with advanced cancer. The project is part of a larger research project, the **A**ctivity, **C**ancer, and **Q**uality of Life at Home project (ACQ project).

People are increasingly living longer time with advanced cancer, but research shows that they have difficulties performing their activities of daily living (ADL) tasks at home, and many people with advanced cancer do not receive the help they need. Overall, this situation may have a significant, negative bearing on these persons' health-related quality of life (HRQoL). One of the aims of occupational therapy is to support occupational performance, viz. ADL task performance. This can be achieved by employing occupation-focused and/or occupation-based interventions. However, existing evidence regarding the efficaciousness of occupation-focused and/or occupation-based interventions in people with cancer is scarce. There is accordingly a need to develop an occupation-focused and/or occupation-based intervention that can help these people to manage their daily life at home. The 'Cancer Home-Life Intervention' was therefore developed based on results from a cross-sectional study, a scoping review of existing evidence and clinical guidelines. The target group and the intervention providers (occupational therapists) shared their views on the intervention and found it relevant. The efficacy was evaluated in a full-scale randomised controlled trial (RCT).

**Objective:** The present PhD project aimed to examine if the 'Cancer Home-Life Intervention' as a supplement to usual care was more efficacious in terms of occupational performance, autonomy and participation and HRQoL than usual care alone in people with advanced cancer living at home.

The study had three specific aims, viz. to: 1) describe the evaluation plan, 2) investigate the efficacy of the 'Cancer Home-Life Intervention' with regard to ADL motor ability, ADL process ability, difficulties performing prioritised occupations, autonomy and

participation, and HRQoL, and 3) identify whether some subgroups of people with advanced cancer gained an effect of the 'Cancer Home-Life Intervention'.

**Design:** An RCT with 6 and 12 weeks of follow-up.

**Material**: A total of 242 home-living adults (≥18 years) with advanced cancer having a World Health Organisation (WHO) Performance Status 1-2 (indicating functional limitations) were randomised either to the intervention group (n=121) or the control group (n=121).

**Outcomes:** The primary outcome was motor skills observed during occupational performance, viz. ADL motor ability measured by the Assessment of Motor and Process Skills (AMPS). Secondary outcomes were ADL process ability measured by the AMPS, difficulties performing prioritised occupations assessed by the Individually Proritised Problem Assessment (IPPA); autonomy and participation assessed by the Danish version of the Impact on Participation and Autonomy Questionnaire (IPA-DK of the IPAQ); and HRQoL assessed by the European Organisation for Research and Treatment of Cancer Quality-of-Life Questionnaire Core-30 (EORTC QLQ C-30).

**Results:** Overall, 191 participants completed the final follow-up at 12 weeks, which was sufficient to reach the required sample size (N=184). No statistically significant effect of the 'Cancer Home-Life Intervention' was found on either the primary outcome or the secondary outcomes. The subgroup analyses showed no statistically significant effect on ADL motor ability in the six subgroups defined by age, gender, years of education, type of primary tumour, functional limitations and problems performing prioritised occupations. No modifying effect of age (0.30 [95% CI: -0.05 to 0.64]) and gender (0.23 [95% CI: -0.11 to 0.57]) was found.

**Conclusion and future research:** The 'Cancer Home-Life Intervention' delivered mostly through one home visit and one follow-up telephone contact produced no effect on the participants' occupational performance, autonomy and participation and HRQoL. There was no subgroup effect of the 'Cancer Home-Life Intervention' on ADL motor ability, but there were some indications that participants aged <69 years benefited more than those aged ≥69 years. However, there may be significant flaws in the design of the intervention that need to be taken into account. Future research needs to identify the appropriacy of the intensity, duration and timing of the intervention, and define the link

between the intervention and the outcomes. Furthermore, future studies should also pay more attention to feasibility testing prior to proceeding to a full-scale RCT. More research is therefore needed to determine the beneficial constribution of an occupation-focused and occupation-based intervention in people with advanced cancer.

## Danish summary

**Titel:** Effekt af ”Bedre hverdag med kræft” til personer med fremskreden kræft i eget hjem: en aktivitetsfokuseret og aktivitetsbaseret intervention.

Dette studie undersøgte effekten af interventionsprogrammet ”Bedre hverdag med kræft” til personer med fremskreden kræft. Projektet var en del af et større forskningsprojekt ”Aktivitet, kræft og livskvalitet i eget hjem” (AKT-projektet).

Mennesker lever længere tid med fremskreden kræft. Eksisterende forskning viser, at personer med fremskreden kræft ofte har betydelige problemer med at klare almindelig daglig livsførelse (ADL). En stor andel oplever desuden, at de ikke får den hjælp, de har behov for. Samlet formodes disse problemer at have negative konsekvenser for deres livskvalitet. Ergoterapeuter har særligt fokus på at støtte mennesker i at klare deres ADL. Til dette arbejde kan ergoterapeuter bruge aktivitetsfokuserede og/eller aktivitetsbaserede indsatser, der kan støtte personer med fremskreden kræft i bedre at klare hverdagen i eget hjem. Forskningen på området er sparsom, og det er derfor nødvendigt at undersøge effekten af aktivitetsfokuserede og/eller aktivitetsbaserede indsatser over for denne målgruppe. AKT-projektet har i et tværsnitsstudie kortlagt de problemer og behov, som personer med en fremskreden kræftsygdom har i eget hjem. På baggrund af resultaterne fra dette, et scoping review, kliniske retningslinjer samt involvering af målgruppen og ergoterapeuter blev programmet ”Bedre hverdag med kræft” udviklet.

**Formål:** Studiets overordnet formål var at undersøge, om ”Bedre hverdag med kræft” som supplement til den sædvanlige indsats havde større effekt på aktivitetsudførelse, autonomi og deltagelse og livskvalitet end kun den sædvanlig indsats hos personer med fremskreden kræft i eget hjem.
Ph.d.-projektet havde tre delformål: 1) at beskrive den planlagte evaluering, 2) at undersøge effekten af ”Bedre hverdag med kræft” på ADL-evnen, graden af besvær med at udføre prioriterede aktiviteter, autonomi og deltagelse, og livskvalitet, 3) at undersøge om ”Bedre hverdag med kræft” havde større effekt på motorisk ADL-evne hos nogle grupper af personer med en kræftsygdom end hos andre.

**Design:** Studiet var et randomiseret kontrolleret studie (RCT) med 6 og 12 ugers opfølgning.

**Metode:** 242 personer med fremskreden kræft (≥18 år) og med en World Health Organisation (WHO) Performance Status 1-2 (indikerer funktionelle begrænsninger) blev randomiseret til enten interventionsgruppen (n=121) eller kontrolgruppen (n=121).

**Udfald:** Det primære udfald var motorisk ADL-evne. Sekundære udfald var procesmæssig ADL-evne, besvær med at udføre prioriterede aktiviteter, autonomi og deltagelse, og helbredsrelateret livskvalitet.

**Resultater:** 191 deltagere gennemførte 12-ugers opfølgningen, som var tilstrækkelig til at opnå den forventede styrke (N=184). Vi fandt ingen statistisk signifikant effekt på hverken det primære eller de sekundære udfald. Der var heller ingen statistisk signifikant effekt i subgrupperne alder, køn, uddannelsesvarighed, type af primære tumor, funktionelle begrænsninger eller aktivitetsproblemer. Alder (0.30 [95% CI: -0.05 to 0.64]) og køn (0.23 [95% CI: -0.11 to 0.57]) modificerede ikke effekten af "Bedre hverdag med kræft" på motorisk ADL-evne ved 12-ugers opfølgning. Der var dog indikationer på, at personer under 69 år havde større effekt af "Bedre hverdag med kræft" end personer over 69 år.

**Konklusion og fremtidig forskning:** "Bedre hverdag med kræft" blev oftest leveret ved ét hjemmebesøg og én opfølgende telefonkontakt. Interventionen havde ingen effekt i forhold til deltagernes aktivitetsudførelse, autonomi og deltagelse eller deres helbredsrelaterede livskvalitet. Der var desuden ingen subgruppe-effekt af "Bedre hverdag med kræft" på motorisk ADL-evne, men der var indikationer på, at deltagere <69 år havde bedre effekt end dem ≥69 år. Der var dog betydelige mangler i udviklingen af interventionen, som skal tages i betragtning. Fremtidig forskning skal identificere den mest effektive intensitet, varighed og timing samt definere sammenhængen mellem interventionen og de valgte udfald. Fremtidige studier skal prioritere at gennemføre et pilotstudie, før der gennemføres et stort RCT. Der er derfor brug for mere forskning til at fastslå den givne effekt af en aktivitetsfokuseret og aktivitetsbaseret intervention til personer med fremskreden kræft.

# Introduction

***"I don't manage to do very much; and you know it's probably because you get this kind of wake-up call about what is important and what isn't; and I do know that it is important to vacuum, but to me, it really doesn't mean that much"***

(participant, Mona, mother of two children)

This quote shows that different tasks have different meaning for different persons; meaning of tasks are shaped by their values, interests, roles, habits and performance capacity (4). Thus, the importance of task performance may vary among different kinds of persons. This can be explained in terms of occupation, which is engagement in meaningful and/or purposeful tasks (1). Occupation is seen as a fundamental human need in similar vein as getting food and sleep (5, 6). However, people may experience problems performing their occupations when confronted with different kinds of diseases, such as cancer. This may, in turn, lead to problems managing their daily life at home (7-10). Although some people with cancer have limited time left, they still value to be engaged in occupational performance (11, 12). The present PhD project aimed to support occupational performance in people's home environment.

Occupational performance (i.e. meaningsful and/or purposeful doing) unfolds as a dynamic interaction between the person, the task and the environment (1, 13). It can be assessed using observation as well as instruments based on self-report (1, 8). Observable occupational performance consists of occupational skills that are the smallest observable, goal-directed actions a person performs during occupational performance. These skills consist of *motor skills*, *process skill* and *communication and interactions skills* (1). Motor and process skills are universal goal-directed actions as they are included in all tasks, e.g. when a person is cooking, changing the sheets or cleaning the bathroom. The person needs to *reach, grip* and *lift* task objects (motor skills); *search* and *locate* tools and materials; *gather* them into an *organised* workpace; and logically perform each *sequence* of the task steps (process skills) (3). The present PhD project investigates the motor skills and process skills that unfold during occupational performance within personal activities of daily living (PADL) and instrumental activities of daily living (IADL). The ability to perform PADL and IADL tasks is fundamental for independent living (3), but is often reduced among people living with a chronic and/or life-threatning disease, e.g. cancer (7-10). A decreased ability to perform ADL tasks may lead to reduced health-related quality of life (HRQoL) for people with cancer (12, 14, 15).

***Cancer and advanced cancer***

Cancer is considered to be one of the most life-threatening and disabling diseases (16, 17). Worldwide, approximately 13.9 million people are living with cancer (18); and in 2012, 14.1 million new cases and 8.2 million deaths were observed (16). In recent years, mortality from cancer has decreased globally (19).

The incidence of cancer in Denmark has been increasing during the past couple of years with 33,800 incident cases in 2007 and 39,100 incident cases in 2014 (20). This trend is expected to continue in coming years (21). However, Danish survival data show that 5-year survivial rates have improved for both men and women in almost any cancer type (21) wherefore a growing number of people are living longer with cancer (22). Danish estimates show that out of 5.7 million citizens about 280,000 people were living with cancer by the end of 2014. Still, 15,427 people in Denmark die yearly from cancer (23). These people most likely had cancer in advanced stages. However, we have no knowledge of the actual number of people living with advanced cancer, defined as incurable cancer, in Denmark (24). Advanced cancer may be caused by metastasis from the primary cancer or primary recurrence with no possibility of curative treatment (24). The majority of people living with advanced cancer prefer to spend most of the remaining time of their life at home, (25, 26), which also is increasingly necessary because of limited healthcare resources (27). In order to manage life at home, it is fundamental to be able to perform ADL tasks (2).

***The difficulties and needs with daily life of people with advanced cancer***

Research shows that people with advanced cancer have difficulties performing ADL tasks at home (10, 11, 28-31) and that being able to perform these tasks is important to them (29, 32-35). Up to 74% of people with advanced cancer (N=163) encounter these difficulties (28); and people with advanced cancer (N=202) in particular have been found to have ineffective motor skills, such as bending (16%), lifting (23%) and walking (13%) (29). ADL tasks that often cause difficulties in people with advanced cancer are cleaning, putting on socks and shoes and picking up clothes (10). Even if people with advanced cancer are unable to perform ADL tasks in the same way as before they fell ill, they still wish to engage in occupations that give them pleasure and an experience of competence (11). Studies report, however, that people with advanced cancer have unmet needs regarding getting the support they need with their ADL tasks (31). More specifically, 10-30% of people with advanced cancer (N=246) report

needing help with housework and preparing meals, 31% fear losing their independence and 14%-46% report inability to perform the tasks they used to do (30). The **A**ctivity, **C**ancer, and **Q**uality of Life at Home (ACQ) cross-sectional study (N=164) (36) showed that the observable occupational performance of people with advanced cancer was characterised by increased effort and reduced efficiency, safety and independence. More than 75% of the participants needed assistance with their ADL tasks, and they spent 60% of their day performing PADL tasks such as eating, dressing and grooming (37). Furthermore, the mean number of problems encountered when performing their prioritised occupations was 3.7 and was within the following domains: 1) *community, social and civic life* (e.g. socialising, doing hobbies and travelling); 2) *domestic life* (including IADL); and 3) *mobility* (e.g. walking, moving around and cycling) (38). Overall, this situation may have a significant, negative bearing on these people's daily life at home, most likely leading to reduced HRQoL (12, 14, 15).

Summing up, existing research shows that people with advanced cancer face difficulties and needs with ADL tasks which may have serious consequences for the remaining time of their life at home. Furthermore, they have problems with their prioritised occupations and show increased physical effort/fatigue, inefficiency (using extra time) and/or safety risks during the observable occupational performance, viz. ADL task performance. One of the aims of occupational therapy is to support people to perform ADL (39), including helping them manage daily life at home.

***Occupational therapy interventions***

Occupational therapy is a client-centred health profession that supports people perform those occupations they need to perform, want to perform and are/or expected to perform. Its overall aim is to enhance their HRQoL and increase their participation in society (1). Occupational therapists (OTs) use a holistic and client-centred approach to identify specific problems encountered in daily life. This means that the individual and the OT collaborate closely to identify those occupations that are important to target in the intervention (1). The intervention components are therefore often tailored to the individual (39).

The keystone in occupational therapy is occupation (40), wherefore the interventions need to use occupation as terapeutic means to improve occupational performance. This can be achieved by employing occupation-focused and/or occupation-based approaches in relation to both evaluation and intervention (3).

Occupation-focused and/or occupation-based interventions can be delivered as an individual intervention (41), a group-based intervention (42) or a combination of individual and group-based interventions (43). The following section describes current evidence of occupation-focused and/or occupation-based interventions in people with cancer.

***Existing evidence of occupation-focused and/or occupation-based interventions for people with cancer***

Only three occupation-focused and/or occupation-based intervention studies were identified in people with cancer; a pilot randomised controlled trial (RCT), a feasibility RCT and a full-scale RCT (41, 44-46).

In 2006, Harrison-Poul et al. (44) conducted a pilot RCT (N=20) where they examined the effectiveness of an occupation-focused intervention in people with advanced cancer. The intervention was divided into minimum five sessions each lasting 3.75 hours. The main aim of the intervention was to enable the participants' occupations by instructing them in energy conservation, relaxation techniques and providing assistive technology. The control group received no occupational therapy intervention. Harrison-Poul et al. (44) were not able to draw any conclusions due to problems with recruiment and a large dropout. At recruiment, potential participants reported being either too well or too ill to receive an occupation-focused intervention. During the 6-week and 12-week follow-up, the participants became too ill to remain in the study (44).

In a feasibility RCT (N=31) from 2011, Hegel et al. (45) conducted a telephone-delivered, occupation-focused intervention in women with breast cancer. A treatment session of problem-solving included six steps: 1) identification of the participants' important occupations; 2) goal setting; 3) brainstorming on possible solutions; 4) analysis of each solution in order to evaluate its feasibility; 5) choosing a solution; and 6) implementing the solution. The intervention used the Person, Environment, Occupation Model to brainstorm on possible problem-solving solutions. Furthermore, the OT encouraged each participant to do physical exercises and stress management. The intervention was provided weekly during a 6-week period. The first treatment session (session 1) lasted on average 71 minutes, while the follow-up session (steps 2-6) lasted on average 35 minutes. Thus, the intervention was provided during two treatment sessions. The control group received care management, rehabilitation, palliative care or/and other services in their communities. The intervention seemed to improve HRQoL

at the 6-week follow-up, emotional state at both the 6-week and the 12-week follow-up and function at the 12-week follow-up (45). However, occupation-focused and/or occupation-based outcomes were not used.

Lastly, in a full-scale RCT (N=118) in 2014, Lindahl et al. (41, 46) included different types of occupation-focused and occupation-based interventions (e.g. assistive technology, prioritise tasks and home modification). All participants' problems and needs with their occupations were assessed by an OT, and the resultant number of sessions was tailored to each participant. The intervention was given as a supplement to usual care. The vast majority of participants in the intervention group received 1-3 treatment hours by the OT. The control group did not receive occupational therapy interventions. The study revealed no effect on HRQoL and self-reported ADL ability, probably because of insufficient statistical power and a sizeable dropout rate (41, 46).

Overall, existing evidence regarding efficacious occupation-focused and/or occupation-based interventions in people with cancer is scarce and inconclusive (41, 44-46). The studies either lacked statistical power (41, 46) or focused on feasibility testing rather than evaluated the overall effect of the interventions (44, 45). Moreover, only the pilot RCT by Harrison-Poul et al. (44) was conducted in people with advanced cancer, yet only people with lung cancer and hepatobiliary cancer. This suggests that current evidence of occupation-focused and/or occupation-based interventions in people with advanced cancer is very much in a premature phase. The above studies did, however, show that it was feasible to conduct such interventions in people with cancer (41, 44-46), even if two of the studies had problems with recruitment and drop-out during the study period (41, 44, 46). Only two of the studies used ADL ability as an outcome and both used self-reported instruments (41, 44, 46). However, several studies show that instruments based on self-report and observation provide distinct but supplementary information about a person's ADL task performance (8, 9). When evaluating occupational performance, both methods, therefore, need to be used. Overall, research into what kind of occupation-focused and/or occupation-based intervention is efficient in people with advanced cancer is urgently needed. The 'Cancer Home-Life Intervention' was therefore developed.

***Development of an occupation-focused and/or occupation-based intervention***
The development process followed five phases:

Phase 1: A synthesis of existing knowledge and evidence was made by including findings from both the cross-sectional ACQ project study (36) and a literature search. The literature search was performed in June 2014 in order to identify home-based intervention studies publised in the past ten years aiming at enabling the occupations of people with cancer. The literature search was performed in PubMed and Cinahl. Additionally, hand search was conducted in the following journals: *the American Journal of Occupational Therapy*, *the Australien Occupational Therapy Journal*, *the British Journal of Occupational Therapy*, *the Scandinavian Journal of Occupational Therapy* and *Clinical Rehabilitation*. The literature search identified the same occupation-focused and/or occupation-based interventions as mentioned earlier (41, 44-46). The literature search was extended to also include people with chronic diseases and older people. This produced a few additional studies (47-51). They consisted mainly of adaptation of occupations, energy conservation, provision of assistive or mainstream technologies, and home modifications, resulting in improved ADL ability and HRQoL (47-51). Available OT clinical guidelines and position statements within the cancer field were also included in the synthesis of existing evidence (39, 52-55).

Phase two: An intervention approach was selected. The selection of an intervention approach was based on the evidence synthesis from phase 1, which showed that an adaptive approach would be relevant for people with advanced cancer. An adaptative approach is particularly applicable for people with advanced cancer since they gradually become more affected by their disease as time passes (56) and may continually need to adjust their occupational performance in order to adapt succesfully to a changeable life situation. Thus, the interventions must be geared to meet the need for increasing compensation through adaptive approaches (57). Adaptation is a kind of a coping strategy that exists in all people. This strategy is applied when we encounter challenges with daily life that require us to change the way we usually do things (57). According to Ingrid Söderback, adaptive interventions include both intrinsic and extrinsic adjustments (58). Intrinsic adjustment is a process where a person receives support to change habits and behaviour to overcome challenging situations. Extrinsic adjustment encompasses changing the person's physical home environment and providing devices or tools in order to enhance occupational performance. She suggests that specific

adaptive interventions include four strategies: 1) *Intrinsic adaptation* (enhance motivation and adjust skills, habits and behaviour), 2) *Occupational adaptation* (support persons to perform occupations in other ways), 3) *Temporal adaptation* (balance use of time and reschedule daily rutines*)* and 4) *Environmental adaptation* (housing adaptation, accessibility, assistive technology and social environment) (58).

Phase three: An adaptive, occupation-focused and occupation-based intervention programme was developed, the 'Cancer-Home Life Intervention'. This intervention is an individual, tailored intervention delivered by OTs over a period of 3 weeks that aims to enable the participants' occupations at home (e.g. engagement in leisure and ADL). It consists of six occupation-focused and/or occupation-based components. The details of the intervention will be described in the method section.

Phase four: Two people with advanced cancer shared their views on the intervention and found it relevant. Subsequently, the intervention was tested in four people with advanced cancer who had no further additions to its contents.

Phase five: The OTs who delivered the intervention to the four participants provided no new information to the contents of the intervention.

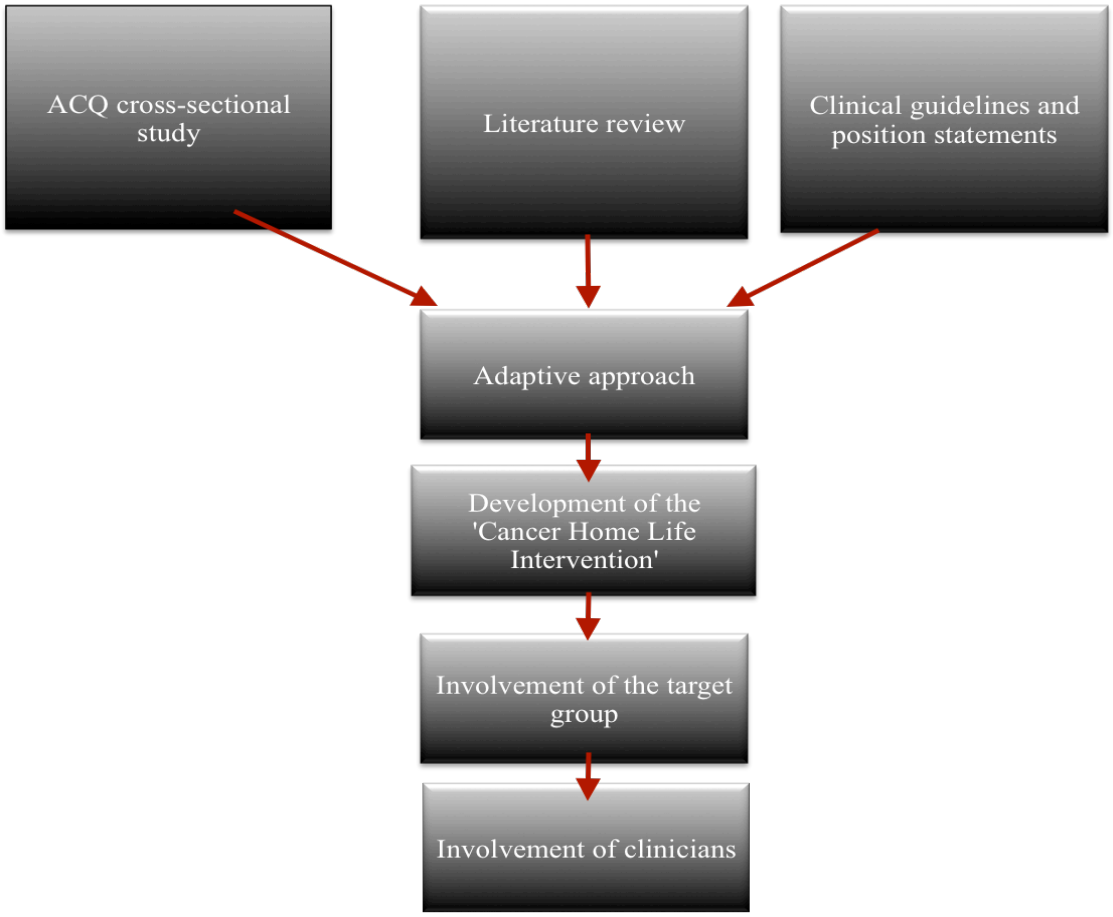


Figure 1: The development and teastning of the ‘Cancer Home-Life Intervention’.

**Summary of introduction**

People live longer with advanced cancer, but research shows that they face difficulties with their ADL tasks at home. Furthermore, people with advanced cancer also demonstrate an increase in physical effort/fatigue, inefficiency and/or safety risks during observed occupational performance and experience difficulties performing their prioritised occupations. Overall, this may have unfavourable consequences for their HRQoL. Occupational therapy is a health profession specifically targeting peoples' occupations, among others through occupation-focused and/or occupation-based approaches in order to support occupational performance. Evidence of occupation-focused and/or occupation-based interventions in people with advanced cancer is, however, lacking. Still, some studies have demonstrated that it is feasible to conduct this kind of intervention in this target group. The 'Cancer Home-Life Intervention' was therefore developed, and the present PhD project will evaluate its efficacy in the context of a full-scale RCT. If the trial shows that the intervention is beneficial, this knowledge will possibly shape future occupational therapy interventions in palliative services for people living with advanced cancer.

# Objective

The overall objective of the study was to evaluate the efficacy of the 'Cancer Home-Life Intervention' compared with usual care alone on occupational performance, autonomy and participation, and HRQoL in people with advanced cancer living at home. The study had three specific aims:

**Paper 1:**

*Aim:* To describe the evaluation plan for the efficacy of the 'Cancer Home Life Intervention'.

**Paper 2:**

*Aim:* To examine the efficacy of the 'Cancer Home Life Intervention' with regard to participants' observed ADL motor ability, observed ADL process ability, self-reported difficulties performing their prioritised occupations, autonomy and participation, and HRQoL.

**Paper 3:**

*Aim:* To identify subgroups of people with advanced cancer who may have gained positive effect of the 'Cancer Home-Life Intervention' on ADL motor ability.

# Methods

This section describes the evaluation plan for the part of the study that examines the efficacy of the 'Cancer Home Life Intervention'; this section is primarily based on Paper I.

***Study design***

The study is a rater-blinded, parallel-group, two-armed RCT with a 6- (T2) and 12-week follow-up (T3). The participants were given the 'Cancer Home-Life Intervention' as a supplement to usual care (intervention group) or usual care alone (control group). The OTs (D-OTs) collecting the data and assessing the outcomes as well as the researcher who performed the analyses were blinded for group allocation. Blinding of the participants was impossible given the type of intervention.

***Setting and participants***

Between January 2015 and October 2016, eligible patients were recruited from oncology departments at Aarhus University Hospital (AUH), Denmark, and Odense University Hospital (OUH), Denmark, comprising in total one outpatient radiotherapy clinic, two outpatient chemotherapy clinics, one bed ward and one palliative care unit with inpatient and outpatient functions. Inclusion criteria were: 1) ≥18 years; 2) diagnosed with advanced cancer by the oncologist responsible for their treatment; 3) living at home or in sheltered living within a maximum radius of 60 km from the AUH or on the island of Funen; 4) able to speak and understand Danish to be able to fill out questionnaires and participate in interviews; and 5) a World Health Organisation (WHO) Performance Status (PS) score of 1 or 2. WHO PS1 represents a patient who is restricted when performing physically demanding tasks, but is ambulatory and able to manage tasks of a lighter nature such as light house work. WHO PS2 represents a patient who is ambulatory, able to manage self-care and is awake more than 50% of waking hours but cannot perform work tasks (59). Patients who lived in nursing homes or hospices, were cognitively impaired or had insufficient Danish language skills were excluded.

***Recruitment***

Hospital nurses, secretaries and the palliative care unit first screened potential participants for eligibility. Eligible patients interested in the study were given oral and written information about the study by project OTs (P-OTs) responsible for enrolment

of participants at each hospital. All enrolled participants provided written consent to participate in the study. Within 1 week after written consent to participate was obtained, participants received a phone call by a trained D-OT. The D-OT again explained the purpose of the study and arranged the date of the baseline visit (T1) in the participant's home.

***Randomisation***

After the T1 visit, the D-OT registered the participants in an online computer-generated randomisation schedule set up by the Odense Patient Data Explorative Network (OPEN), allocating them to either the intervention group or the control group in a 1:1 ratio. OPEN had otherwise no involvement in the study. The participants were assigned in fixed block sizes that were concealed for the research group and for the D-OTs. The randomisation was stratified by hospital (AUH, OUH and palliative care unit at OUH). Participants in the intervention group were contacted by telephone within 2 days after randomisation.

***Intervention***

*The 'Cancer Home-Life Intervention'*

As described in the Introduction, the 'Cancer Home-Life Intervention' is an adaptive, occupation-focused and occupation-based programme delivered by OTs in the homes of people with advanced cancer. The intervention aims to enable those occupations the participants would like to perform at home (e.g. engagement in leisure and ADL). This means that the OT and the participant collaborate to identify those occupations that are important to target in the intervention, and these occupations become the main target of the intervention. The OT provides the participants with adaptive strategies that should compensate for their functional limitations and enable them to perform their selected occupations with less difficulty. These adaptive strategies are in line with Ingrid Söderback's four strategies mentioned in the Introduction (58). The intervention consists of the following six components: 1) a mandatory interview to clarify problems and needs with their occupations at home; 2) prioritisation of resources, energy and tasks; 3) adaptation of occupations; 4) adaptation of posture and seating positioning; 5) provision of assistive technology; and 6) modification of the physical home environment. Component 1 is mandatory while the composition of the remaining components is optional, meaning that they are tailored to each participant based on their selected occupations identified in component 1. Table 1 describes the content of each

component in more detail. The participant is given instructions in and practice of the selected adaptive strategies. This includes that the OT observes the participants while they perform their selected occupations (component 3 and component 5). In total, 1-3 home visits (max 2 hours) and 1-3 follow-up telephone contacts are offered. The scheduling of these visits and contacts is also tailored to the participants' needs. The telephone contacts were made in order to support the participants' use of the selected adaptive strategies when performing their selected occupations and to resolve new problems they might face in-between the home visits.

Table 1: Description of the 'Cancer Home-Life Intervention'.

| Intervention features | | Intensity and content | |
|---|---|---|---|
| Setting | | Participant's home | |
| Format | | Individual | |
| Intervention provider | | Occupational therapist | |
| Number of home visits | | 1-3 | |
| Intervention period | | ≤3 weeks | |
| Time per visit | | 60-120 min. | |
| Telephone follow-up | | 1-3 | |
| **Mandatory component** | | **Occupation-focused** | **Occupation-based** |
| Component 1:*Initial interview* | Identify those occupations the participants would like to perform at home. The baseline findings from the selected outcomes were included by the I-OT when the participant-selected occupations were identified. The I-OT and the participant schedule an intervention plan together. They select which of the five optional components that should be included, tailoring the intervention to the participants' needs with their selected occupations. | Yes | No |
| **Optional components** | | | |
| Component 2: *Prioritisation of resources, energy and tasks* | Instructing participants in energy conservation techniques, talking about time to rest during the day and delegating tasks to family members or other people, for instance, so that participants can perform and participate in their selected occupations. | Yes | No |
| Component 3: *Adaptation of occupations* | Instructing and sometimes observing participants while they perform their selected occupations in alternative ways to manage symptoms, e.g. by working in a seated position instead of standing, splitting tasks into actions, reordering actions and asking for assistance. | Yes | Sometimes |
| Component 4: *Adaptation of posture and seating positioning* | Instructing participants in seated positioning and ergonomics when they perform their selected occupations, e.g. lifting techniques, how to obtain a good seating/standing position during occupational performance, and how to obtain a good resting position in bed or other places. | Yes | No |
| Component 5: *Provision of assistive technology* | Selecting assistive devices for participants and instructing and observing them when performing selected occupations, e.g. mobility devices, devices for gardening, devices for handling cold objects. | Yes | Yes |
| Component 6: *Modification of the physical home environment* | Providing home safety and home modification, e.g. rearranging furniture or setting up handrails, and ensuring home safety. | Yes | No |

*Training of intervention providers*

The content of the intervention was standardised in an intervention manual (see Appendix A). In good time prior to a 1-day workshop, the intervention manual was distributed to six intervention occupational therapist (I-OTs) for preparation. At the workshop, the I-OTs had opportunity to discuss the diffent parts of the manual with the developers and each other. In order to enhance the fidelity of the manual, several meetings with the I-OTs and the developers were scheduled during the study period.

***Usual care***

The control group solely received usual care. Usual care can consist of palliative care and/or rehabilitation, sometimes involving occupational therapy, including assistive technology and home modification interventions, but not necessarily provided systematically.

***Data-collection***

Eight blinded D-OTs collected the following baseline data from each participant using a study-specific questionnaire: age, gender, living alone, type of residence, years of education and number of comorbidities. The D-OTs collected data at T1 and at T3 in the participants' homes using interviews, questionnaires and/or observations. T2 data were collected using a postal questionnaire and a telephone interview. At T1, the participants were told not to reveal their group allocation to the D-OTs during the two follow-up sessions. The D-OTs took part in a 1-day workshop with two members of the research team. Prior to the workshop, they received a data collection manual which outlined how to collect the data in the participants' homes (see Appendix B). Data collection was regularly monitored by the study coordinator (myself) in order to achive high-quality data.

The I-OTs reported which components they provided to each participant, the number of components, the number of telephone contacts, the time used at each visit and the participant-selected occupations. Participants in both the intervention group and the control group were asked to systematically register interventions they received during the study period, including interventions provided by OTs.

### *Outcomes*

#### *Two aspects of occupational performance*

*Observed ADL task performance*

The Assessment of Motor and Process Skills (AMPS) is a standardised, observation-based assessment instrument measuring a person's observed overall quality of ADL task performance (3). A calibrated D-OT observes 16 motor skills and 20 process skills while a person performs two standardised ADL tasks of relevance to the person's daily life. Each skill is scored on a four-point ordinal scale. The ordinal scores are converted into two linear measures of ADL motor and ADL process ability expressed in logistically transformed probability units (logits) adjusted for rater severity, ADL task challenges and skill item difficulty. The transformation is based on a many-faceted Rasch measurement model. The ADL motor ability measure expresses the amount of physical effort, clumsiness and/or fatigue a person demonstrates during ADL task performance. The ADL process ability measure expresses the overall efficiency regarding appropriate use of time, space and objects throughout ADL task performance. Higher positive measures represent better ADL task performance. ADL motor ability measures above 2.0 logits and ADL process ability measures above 1.0 represent competent ADL task performance, and 0.3 logits on both measures indicate a clinically relevant change (3). During the entire study period, AMPS data were being validated by the Centre for Innovative OT Solutions (CIOTS). Studies support that the AMPS can provide valid and reliable measures among people with advanced cancer (60, 61) and have also demonstrated good responsiveness (3).

*Self-reported performance of prioritised occupations*

The Individually Proritised Problems Assessment (IPPA) is used to assess self-reported occupational performance. The IPPA is a generic, structured interview-based instrument that is used to identify the participants' prioritised occupations and to assess their subjective experience when performing these occupations (62). The instrument has primarily been used to evaluate the effectiveness of assistive technology provision (63, 64). In the present PhD project, the participants prioritise up to seven occupations in the home environment, and rate both the importance and difficulty of each occupation on a five-point ordinal scale from 1 to 5, where 1 = not important at all and 5 = most important; and 1 = no difficulty at all and 5 = too much difficulty to perform the occupation at all. The importance scores and the difficulty scores of each occupation are

multiplied and added together. The scores are then divided by the total number of identified occupations, resulting in the total IPPA score ranging from 1 to 25, with a higher score indicating the participant's average experienced difficulty performing a prioritised occupation. The IPPA has been used in elderly people with assistive devices, and was found to be responsive and valid (63, 64).

***Autonomy and participation***

The Danish version (IPA-DK) of the Impact on Participation and Autonomy Questionnaire (IPAQ) is a generic questionnaire that identifies person-perceived participation restrictions. It consists of five domains: 1) autonomy indoors; 2) family roles; 3) autonomy outdoors; 4) social relations; and 5) work and education (65). Only domains 1, 2 and 4 were used in the present PhD project. The participants' perceived participation restrictions are graded on a four-point ordinal scale ranging from 0 = no participation restrictions to 4 = severe participation restrictions. The IPA-DK has shown to be a valid, reliable and responsive instrument (66-69).

***HRQoL***

The European Organisation for Research and Treatment of Cancer Quality-of-Life Questionnaire Core 30 (EORTC QLQ C-30) is a questionnaire assessing the HRQoL of people with cancer (70). It consists of five multi-item functional scales (physical, role, cognitive, emotional and social), three multi-item symptom scales (fatigue, pain, and nausea and vomiting), a global health status/ quality of life scale and six single-symptom scales (dyspnoea, loss of appetite, insomnia, constipation, diarrhoea and financial difficulties). In the present PhD project, the global health status/ quality of life scale was used as a measure of HRQoL. This scale covers a seven-point response scale ranging from 0 (very poor) to 7 (very good). Each participant's raw ordinal score was converted into a score between 0-100 according to the scoring manual, with higher scores indicating better HRQoL (70). Scores between 5-10 are usually considered to indicate clinically relevant change (71). The EORTC QLQ C-30 is a responsive, valid and reliable instrument among people with advanced cancer (72, 73).

***Primary outcome***

- ADL motor ability as measured at T1 and T3 by the AMPS (3). ADL motor ability was the primary outcome since people with advanced cancer demonstrate increased clumsiness or physical effort or inefficiency during occupational performance (36).

***Secondary outcomes***

- ADL process ability as measured at T1 and T3 by the AMPS (3).
- Difficulty performing their prioritised occupations assessed at T1, T2 and T3 by the IPPA (62).
- Autonomy and participation within the domains Autonomy indoors, Family role and Social relations assessed at T1, T2 and T3 by the IPA-DK (65).
- HRQoL assessed at T1, T2 and T3 by the EORTC QLQ C-30 (70).

***Outcome used in the subgroup analysis***

- ADL motor ability measured with the AMPS (3).

***Subgroups***

As described in the protocol (Paper I), four subgroups (gender, age, primary tumour and WHO PS) were chosen prior to the RCT. The subgroups were chosen since these variables have been found to be associated with ADL (10, 74-77) and may also be associated with a different treatment response to the 'Cancer Home-Life Intervention' (78). Another two subgroups were chosen after analysis of the RCT data (Paper II): problems performing prioritised occupations and years of education. This selection was based on the following two arguments: 1) a large number of participants in the intervention group (N=33 [27.5%]), see Table 2 in Paper 2, page 7-8) reported not having any problems performing their prioritised occupations which may have caused a different treatment response for these participants; and 2) Gitlin et al. (79) found that years of education moderated the effect of their OT-based intervention on ADL among community-living older adults.

Thus, the final six subgroups were categorised as follows: 1) *gender* (men versus women); 2) *age* (<69 years versus ≥69 years as 69 was the median value) ; 3) *primary tumour* (lung, head and neck, gynaecological, prostate, breast, gastrointestinal, bladder and other); 4) *functional level* (PS1 versus PS2); 5) *problems performing prioritised occupations* (yes/no); and 6) *years of education* (≤10 years, 11-12 years, and ≥13 years).

Age, gender and years of education were registered using the study-specific questionnaire. Hospital nurses rated the participants' WHO PS and obtained information on the primary tumour diagnosis from the responsible oncologist. Problems performing prioritised occupations were assessed with the IPPA (62). These six variables were collected at enrolment or at T1.

***Statistical analysis***

A sample size of 184 participants (92 per group) was calculated to provide 80% power to show a between-group clinically relevant change of 0.3 logits in ADL motor ability (3). Based on an anticipated 12-week dropout of 32% (44, 45, 80, 81), the study needed to recruit 272 participants (136 per group). The power calculation was based on a two-sample t-test of normal distribution with a two-sided 5% significance level and a common standard deviation (SD) for ADL motor ability of 0.727 (36).

Mean values and SD, median and interquartile range (IQR), or number and per cent were used to describe the participants' baseline characteristics. The primary analyses consisted of multiple linear regression analyses estimating the between-group mean change in ADL motor ability and ADL process ability from T1-T3. Multiple linear regression analyses were also performed to calculate the between-group mean change from T1-T2 and from T1-T3 in difficulties performing prioritised occupations and HRQoL. The IPA-DK ordinal scores were dichotomised into no perceived restrictions (scores 0 and 1) and perceived restrictions (scores 2, 3 and 4). The probability of no perceived participation restrictions between the intervention and control group within the domains Autonomy indoors, Family role and Social relations was analysed using logistic regression. All analyses were adjusted for hospital, and estimates were stated with 95% confidence intervals (95% CI).

The robustness of the primary analyses was investigated by two sensitivity analyses. Firstly, we performed linear regression analysis adjusted for ADL motor ability, ADL process ability, gender, age, primary cancer diagnosis, education and HRQoL if these variables were unbalanced at T1 between the groups. Secondly, mixed linear models were performed to investigate change over time for all quantitative outcome measures (AMPS, IPPA and EORTC QLQ C-30).

In the subgroup analysis, mean values and SD were used to describe T1 ADL motor ability and T3 ADL motor ability for the intervention group and the control group stratified according to the six subgroups. Between-group mean changes from T1-T3

were calculated for each subgroup with 95% CI. Multiple linear regression was performed with ADL motor ability at T3 as the outcome. The predictors included treatment arm (intervention versus control), baseline ADL motor ability, gender, age, primary tumour, functional level assessed by the WHO PS, years of education and problems performing prioritised occupations assessed by the IPPA. Each predictor was estimated with 95% CI and p values. Interaction terms were added into the model between the treatment and both gender and age since these variables seem to be the most plausible moderators of treatment effect (79, 82). Wald's test was performed to test for a statistically significant interaction.

The participant-selected occupations, which was the main target of the intervention, were categorised using the sub-categories defined by the ADL taxonomy instrument and illustrated using a histogram. (83). Some of the participant-selected occupations differed from the ADL taxonomy sub-categories and were therefore not categorised using the ADL taxonomy instrument.

Statistical data files were saved on a secure SharePoint site at the University of Southern Denmark, and data were entered into the Research Electronic Data Capture (REDCap) (84). AMPS data were entered into the REDCap database twice to avoid biased results due to entering error. To avoid entering error in the remaining outcome data, a random sample of 10% was extracted from the REDCap database and checked for such errors. If there was more than 10% error, we planned to correct data and extract a new random sample. However, this was not the case, and it was therefore not necessary to extract a new random sample. All analyses were performed as complete case analysis, excluding participants with missing values on outcome measures including invalid AMPS data as assessed by the CIOTS. Participants were analysed according to their original randomisation group. In all analyses, model assumptions were assessed using QQ-plot and histogram. A 5% significance level was considered statistically significant. The analyses were performed using STATA version 14.0.

***Ethics and approvals***

The intervention was expected not to cause any adverse effects. However, the data collection and the intervention could potentially cause emotional reactions for the participants as it focused on problems encountered in their daily lives. Since the participants were living with a life-threatening disease, they were vulnerable and could react with tears and anger. The OTs in the study were instructed to handle these

reactions, and during the study they were offered supervision from one of the members of the research team. Furthermore, the participants received a telephone number so that anytime they could get in contact with the OTs. All data were anonymised, and the results were handled confidentially.

The RCT was registered at ClinicalTrials.gov (NCT02356627) and followed the Declaration of Helsinki 2008 (85). The Ethics Committee (S-20122000-96) decided that approval was not necessary. The Danish Data Protection Agency (FN 215-57-0008) approved the data collection and the storing of data.

# Results

Paper I was published prior to conducting the RCT. This section evaluates the efficacy of the 'Cancer Home Life Intervention' and is thus primarily based on Paper II and Paper III.

Overall, 522 patients were invited to participate in the RCT of whom 269 declined to participate due to lack of capability (n=81), lack of relevance (n=96), lack of interest (n=56) or due to other reasons (n=36) (Figure 2). The remaining 11 invited patients were excluded (n=6) or died before the T1 visit (n=5) (see reasons for exclusion in Figure 2). The included participants did not differ statistically significantly from those who declined participation with regard to age ($p = 0.29$), gender ($p = 0.55$), WHO PS ($p = 0.65$) and primary tumour ($p = 0.24$). In total, 242 participants were allocated to the intervention group (n=121) or the control group (n=121).

After randomisation, eight participants declined the intervention (6.6%). The attrition was nearly the same in the two groups (intervention: 8.3% [T2] and 9.9% [T3]) vs. control: 7.4% [T2] and 12.4% [T3]) with death and illness being the main reasons for drop-out. Overall, 191 participants (79%) completed the primary outcome measure at T3. Thus, these participants were included in the subgroup analysis. The numbers included were therefore sufficient to reach the calculated sample size of N=184.

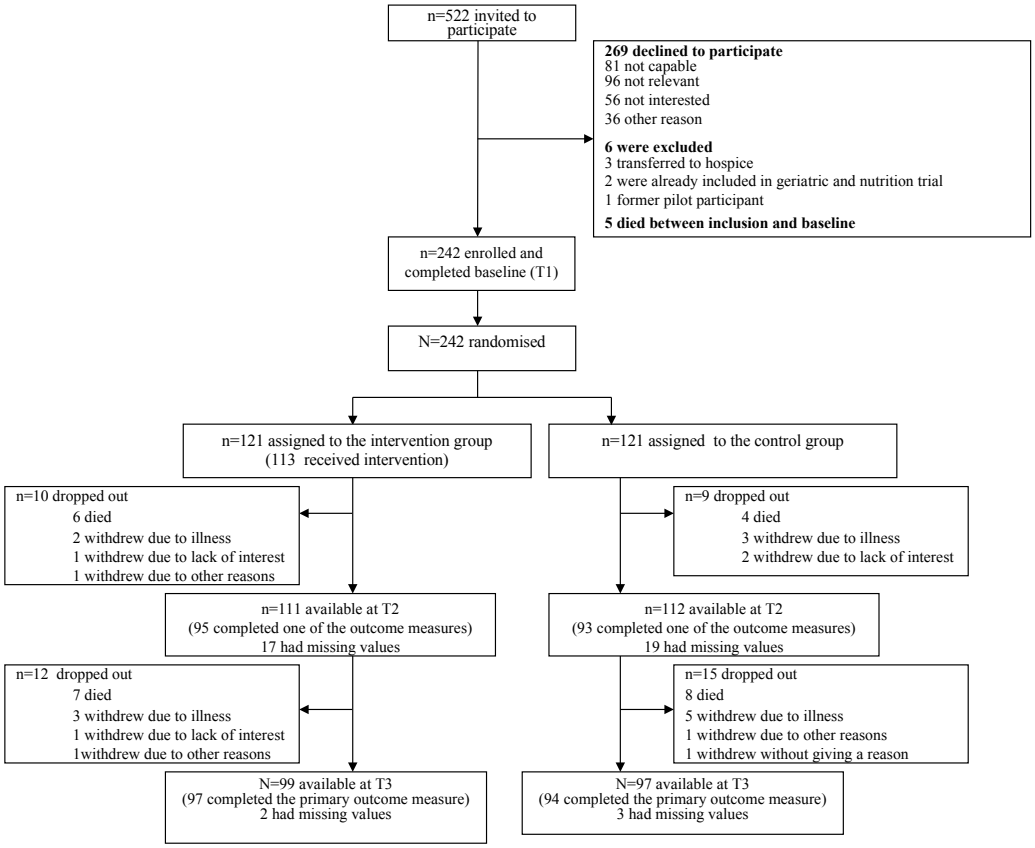


Figure 2: Flow chart.

***Baseline characteristics***

The study population's average age was 67.91 years; men and women were almost equally represented (women n=124 [51.2%]; men n=118 [48.8%]); and participants were mostly living together with a partner (167 [68.9%]), typically in a house (168 [69.7%]). The majority of the participants were recruited from the AUH (AUH n=222 [91.7%]; OUH n=20 [8.3%]). The most frequent primary tumours were gastrointestinal (74 [30.6%]), lung (48 [19.8%]), breast (37 [15.3%]) and prostate (30 [12.4%]) tumours. More than 70% of the participants belonged to WHO PS1. In total, 64 participants (26.6%) reported no problems performing their prioritised occupations assessed using the IPPA. In contrast, nearly all participants (n=230 [95.4%]) had an observed ADL motor ability below the competence cut-off threshold (≤ 2.0 logits) indicating increased clumsiness, physical effort and/or fatigue during ADL task performance (see Table 2 in Paper 2, page 7-8). Generally, there were no large differences between the intervention group and the control group with regard to socio-demographic variables, clinical characteristics or outcome measures. The only observed skewed variable was gender. In all sensitivity analyses, we therefore adjusted for gender (see Table 2 in Paper 2, page 7-8).

***Delivered content of the 'Cancer Home-Life Intervention'***

The intervention participants primarily received component 1 (n = 113; 93.4%), component 2 (n = 73; 60.3%), component 3 (n = 70; 57.9%) and component 5 (n = 65; 53.7%). The median number of delivered components was three. The I-OT conducted more than one visit in the homes of 36 participants (29.8%), and at least half of the intervention participants received one follow-up telephone contact (62 [51.2%]). Detailed information about the delivery of the 'Cancer Home-Life Intervention' can be found in Table 3 in Paper II, page 8.

Figure 3 shows the participant-selected occupations that were the main target of the 'Cancer Home-Life Intervention'. The range of the participant-selected occupations was broad. In addition to occupations within the home, participant-selected occupations outside the home environment were also targeted, e.g. shopping and transportation.

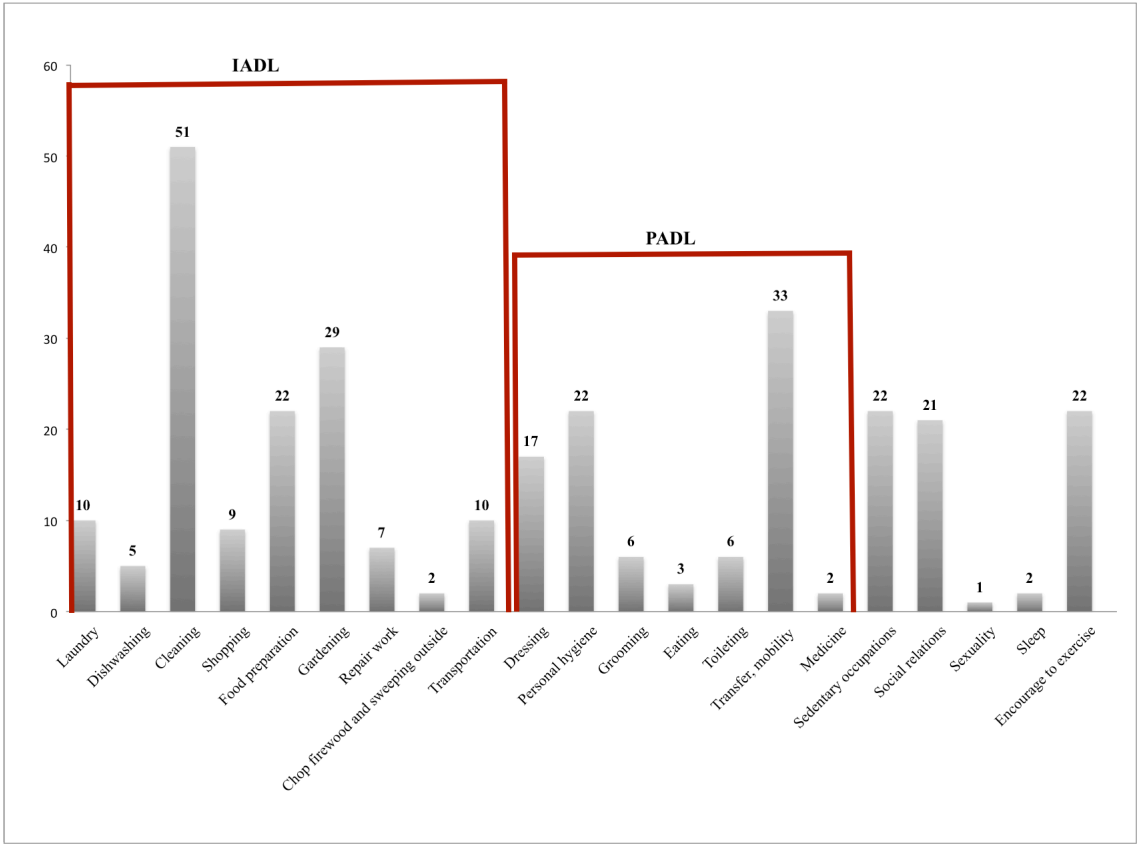

Figure 3: The range of the participant-selected occupations.

### *Efficacy of the 'Cancer-Home Life Intervention'*

*Within-group change over time*

The ADL motor ability and ADL process ability were stable over time in both groups as the decrease was neither clinically relevant (a clinically relevant difference is considered to be 0.3 logits (3)) nor statistically significant (see Table 2, AMPS and Paper II, Figure 2a and 2b, page 9). The participants in both groups experienced statistically significantly less difficulty performing their prioritised occupations over time, both from T1 to T2 and from T1 to T3 (see Table 2, IPPA and Paper II, Figure 2c, page 9). The HRQoL was stable over time in both groups with non-significant estimates which were not clinically relevant (a clinically relevant difference is considered to be between 5-10 points) (71) (see Table 2, EORTC and Paper II, Figure 2d, page 9). The intervention group and the control group had a high probability of encountering no participation restrictions at T2 and T3 in the three domains of the IPA-DK (see Table 3).

*Between-group change over time*

The results of the outcomes are presented in Table 2 and Table 3. There was no statistically significant effect of the 'Cancer Home-Life Intervention' compared with

usual care alone on ADL motor ability from T1-T3, i.e. the primary trial outcome. The between-group mean change was far from being clinically relevant (≥0.3 logits). The conducted sensitivity analyses did not change the results.

Overall, no statistically significant effect of the 'Cancer Home-Life Intervention' was found for any of the secondary outcomes (see Table 2 and Table 3). Sensitivity analyses confirmed the absence of effect ascertained in the primary analysis.

Table 2: Mean change in primary outcomes and secondary outcomes from baseline (T1) to six (T2) and 12-week follow-up (T3); complete case analysis.

| Outcomes | n | Intervention group | n | Control group | Between-group mean change (95% CI) | p value |
|---|---|---|---|---|---|---|
| | | Mean change | | Mean change | | |
| **AMPS** | | | | | | |
| ADL motor ability T1-T3[abcd] | 97 | -0.14 (-0.27 to 0.00) | 94 | -0.10 (-0.24 to 0.05) | -0.04 (-0.23 to 0.15) | 0.69 |
| ADL process ability T1-T3[abcd] | 97 | -0.10 (-0.20 to -0.01) | 94 | -0.04 (-0.14 to 0.06) | -0.06 (-0.20 to 0.07) | 0.37 |
| **IPPA** | | | | | | |
| IPPA score T1-T2[cde] | 67 | -1.27 (-2.01 to -0.53) | 65 | -1.16 (-1.91 to -0.41) | -0.11 (-1.17 to 0.95) | 0.83 |
| IPPA score T1-T3[cde] | 62 | -1.38 (-2.35 to -0.40) | 63 | -1.03 (-2.00 to -0.05) | -0.35 (-1.71 to 1.01) | 0.61 |
| **EORTC QLQ C-30** | | | | | | |
| HRQoL T1-T2[cdfg] | 94 | -1.40 (-5.49 to 2.68) | 93 | -1.19 (-5.39 to 3.01) | -0.21 (-5.97 to 5.54) | 0.94 |
| HRQoL T1-T3[cdfg] | 93 | 1.50 (-2.97 to 5.97) | 90 | 3.11 (-1.52 to 7.74) | -1.61 (-7.95 to 4.73) | 0.62 |

AMPS=Assessment of Motor and Process Skills; ADL=Activities of Daily Living; IPPA=Individually Prioritised Problem Assessment; EORTC QLQ-C30 =European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire C-30; HRQoL= Health-related Quality of Life

[a]Higher positive measures represent better ADL task performance and a clinical relevant change is 0.3 logits

[b]Exponential transformation of the difference between groups did not change the results

[c]Multiple linear regression adjusted for hospital. The estimates are shown in the table

[d]Multiple linear regression adding gender in the model did not change the results and is therefore not shown in table

[e]The IPPA score ranges from 1 to 25, with higher scores indicating a greater degree of difficulty performing prioritised occupations

[f]The global health status/ quality of life scale from the EORTC QLQ C-30 is used to assess HRQoL

[g]The HRQoL ranges from 0 to 100, with higher scores indicating a greater degree of HRQoL

Table 3: Odds-ratio for no perceived participation restrictions; complete case analysis.

| Outcomes | n | Intervention group | n | Control group | Odds ratio for no perceived participation restrictions (95% CI) | p value |
|---|---|---|---|---|---|---|
| | | Odds[b] | | Odds[b] | | |
| **IPA-DK[a]** | | | | | | |
| Autonomy Indoor T2 | 95 | 7.64 (4.07 to 14.32) | 91 | 6.00 (3.36 to 10.79) | 1.27 (0.54 to 3.02)[cd] | 0.59 |
| Autonomy Indoor T3 | 89 | 8.89 (4.46 to 17.71) | 87 | 8.67 (4.35 to 17.28) | 1.03 (0.39 to 2.75)[cd] | 0.95 |
| Family role T2 | 95 | 1.21 (0.81 to 1.81) | 91 | 1.39 (0.92 to 2.12) | 0.83 (0.46 to 1.50)[cd] | 0.54 |
| Family role T3 | 89 | 1.70 (1.10 to 2.61) | 87 | 1.56 (1.01 to 2.40) | 1.08 (0.59 to 1.99)[cd] | 0.81 |
| Social relations T2 | 95 | 18.00 (7.31 to 44.30) | 89 | 13.83 (6.04 to 31.68) | 1.22 (0.35 to 4.21)[cd] | 0.75 |
| Social relations T3 | 89 | 11.71 (5.41 to 25.34) | 87 | 13.50 (5.89 to 30.94) | 0.86 (0.28 to 2.69)[cd] | 0.80 |

IPA-DK=The Danish Version (IPA-DK) of the Impact on Participation and Autonomy Questionnaire (IPAQ);

[a]The IPA-DK was dichotomised into "no perceived participation restrictions" and "perceived participation restrictions"

[b]Odds for no perceived participation restrictions

[c]Logistic regression adjusted for hospital. The estimates are shown in the table

[d]Logistic regression adding gender in the model did not change the results and is therefore not shown in tab

### *Subgroup analysis*

The stratification of the participants into the six subgroups is shown in Table 4. All subgroups' mean ADL motor ability at T1 and T3 was below the competence cutoff (<2.0 logits). Overall, the between-group mean ADL motor ability change from T1-T3 in the subgroups was small, non-significant as the CI included 0, and generally not clinically relevant (≥0.3 logits) (see Table 4).

Tabel 4: Subgroup effect of the 'Cancer-Home Life Intervention' (N=191).

| | T1 mean ADL motor ability[a] (SD) | | T3 mean ADL motor ability[a] (SD) | | Between-group mean change[b] (95% CI) |
|---|---|---|---|---|---|
| Subgroups | Intervention group | Control group | Intervention group | Control group | |
| **Treatment (n=191)** | | | | | |
| Intervention group (n=97) | 1.16 (0.58) | - | 1.01 (0.69) | - | - |
| Control group (n=94) | - | 1.21 (0.58) | - | 1.10 (0.61) | |
| **Age (n=191)** | | | | | |
| <69 (n=95) | 1.19 (0.56) | 1.33 (0.57) | 1.12 (0.52) | 1.08 (0.75) | 0.18 (-0.09 to 0.45) |
| ≥69 (n=96) | 1.13 (0.59) | 1.08 (0.58) | 0.91 (0.82) | 1.11 (0.44) | -0.25 (-0.53 to 0.03) |
| **Gender (n=191)** | | | | | |
| Women (102) | 1.05 (0.64) | 1.17 (0.61) | 1.15 (0.40) | 1.14 (0.61) | 0.13 (-0.10. to 0.37) |
| Men (n=89) | 1.26 (0.49) | 1.26 (0.54) | 0.88 (0.87) | 1.04 (0.62) | -0.16 (-0.46 to 0.15) |
| **Education (n=190)** | | | | | |
| ≤10 years (n=50) | 1.15 (0.68) | 1.09 (0.58) | 0.95 (0.94) | 1.16 (0.42) | -0.27 (-0.73 to 0.19) |
| 11-12 years (n=52) | 1.21 (0.42) | 1.16 (0.53) | 0.94 (0.69) | 0.99 (0.61) | -0.10 (-0.48 to 0.28) |
| ≥13 years (n=88) | 1.12 (0.62) | 1.30 (0.59) | 1.12 (0.47) | 1.11 (0.70) | 0.19 (-0.07 to 0.44) |
| **Primary tumour (n=190)** | | | | | |
| Lung (n=36) | 1.21 (0.44) | 1.08 (0.61) | 1.05 (0.60) | 0.85 (0.78) | 0.07 (-0.49 to 0.64) |
| Head and neck (n=11) | 0.90 (0.56) | 1.06 (0.94) | 0.25 (1.14) | 0.82 (1.16) | -0.41 (-1.90 to 1.08) |
| Gynaecological (n=9) | NA | 1.44 (0.32) | NA | 1.41 (0.35) | NA |
| Prostate (n=25) | 1.29 (0.41) | 1.34 (0.45) | 1.10 (0.48) | 1.17 (0.68) | -0.02 (-0.48 to 0.42) |
| Breast (n=32) | 0.91 (0.41) | 1.03 (0.65) | 1.03 (0.33) | 1.08 (0.43) | 0.07 (-0.31 to 0.44) |
| Gastrointestinal (n=61) | 1.32 (0.59) | 1.44 (0.51) | 1.07 (0.81) | 1.30 (0.41) | -0.11 (-0.47 to 0.26) |
| Bladder (n=12) | 0.64 (1.00) | 1.01 (0.34) | 0.98 (0.50) | 0.97 (0.39) | 0.38 (-0.41 to 1.18) |
| Other (n=4) | 0.95 (0.79) | NA | 1.15 (0.53) | NA | NA |
| **Functional level (n=190)** | | | | | |
| PS1 (n=139) | 1.28 (0.44) | 1.32 (0.51) | 1.12 (0.66) | 1.13 (0.61) | 0.03 (-0.20 to 0.24) |
| PS2 (n=51) | 0.88 (0.75) | 0.83 (0.64) | 0.78 (0.74) | 0.97 (0.62) | -0.24 (-0.65 to 0.18) |
| **Problems performing prioritised occupations (n=191)** | | | | | |
| No (n=57) | 1.47 (0.38) | 1.45 (0.43) | 1.11 (0.74) | 1.20 (0.44) | -0.11 (-0.42 to 0.19) |
| Yes (n=134) | 1.02 (0.59) | 1.11 (0.61) | 0.97 (0.67) | 1.05 (0.67) | 0.01 (-0.20 to 0.24) |

ADL=Activities of Daily Living
NA= Not applicable
T1=Baseline
T2=12-week follow-up
[a]Higher positive measures represent better ADL task performance and below competent cut-off on the ADL motor ability (< 2.0 logits)
[b] A change of ≥0.3 logits on the ADL motor ability indicates a clinically relevant change

Table 5 shows the multiple linear regression with interaction terms. The WHO PS and primary tumour were not included in the multiple linear regression due to the fact that 1) there was collinearity between ADL motor ability and WHO PS at T1 and 2) the size of the primary tumour subgroups was too small. The model found no statistically significant interaction either between treatment groups and age (<69 years versus ≥69 years) or between treatment groups and gender (men versus women). However, we observed a trend for interaction by age as the p value was 0.09 and the CI was 0.64 logits in the upper end and not far below 0 (0.30 logits [95% CI:-0.05 to 0.64], $p$=0.09).

Table 5: Interaction of the Cancer-Home Life Intervention on ADL motor ability at 12 weeks of follow-up.

| Predictors | Adjusted mean ADL motor ability, 12-week follow-up [95% CI] | P values | Interaction with treament groups [95% CI] | P of Interaction |
|---|---|---|---|---|
| **Treatment** | | | | |
| Control group (n=94) | Ref. | | | |
| Intervention group (n=97) | -0.02 [-0.20 to 0.15] | 0.82 | | |
| **Baseline ADL motor ability** | 0.48 [0.32 to 0.64] | <0.000 | | |
| **Age** | | | 0.30 [-0.05 to 0.64] | 0.09 |
| Age <69 (n=95) | Ref. | | | |
| Age ≥69 (n=96) | -0.03 [-0.21 to 0.15] | 0.76 | | |
| **Gender** | | | 0.23 [-0.11 to 0.57] | 0.19 |
| Women (n=101) | Ref | | | |
| Men (n=89) | -0.24 [-0.42 to -0.06] | 0.01 | | |
| **Education** | | | | |
| ≤10 years (n = 50) | Ref | | | |
| 11-12 years (n=52) | -0.08 [-0.32 to 0.16] | 0.54 | | |
| ≥13 years (n=88) | -0.03 [-0.25 to 0.19] | 0.78 | | |
| **Problems performing prioritised occupations** | | | | |
| No (n=57) | Ref. | | | |
| Yes (n=134) | -0.01 [-0.21 to 0.20] | 0.96 | | |

[b] Multiple regression adjusted for age, gender, education, problems performing prioritised, centre and baseline ADL motor ability

***Summary of results***

In summary, the intervention group mainly received one home visit that typically lasted 105 minutes and one telephone contact. The 'Cancer Home-Life Intervention' was mostly targeted at participant-selected occupations within IADL, such as cleaning, gardening and cooking. The 'Cancer Home-Life Intervention' as an add-on to usual care had no effect on any of the outcome measures compared with usual care alone; nor did it have any effect in any subgroups defined by age, gender, years of education, type of primary tumour, functional level and problems performing prioritised occupations. However, there was a borderline significant trend ($p=0.09$) that participants aged <69 years benefitted more than those aged ≥69 years.

# Discussion

This PhD project evaluated efficacy of the occupation-focused and occupation-based programme, the 'Cancer Home-Life Intervention' in people with advanced cancer living at home. In the following section, the main results are discussed in relation to the overall objective of the present PhD project. Subsequently, methodological considerations will be discussed, and the external validity will be discussed at the end of the section.

To my knowledge, the present study is the first full-scale and suffiently powered RCT to investigate the efficacy of an occupation-focused and occupation-based intervention delivered in the home environment of people with advanced cancer. Previous research has been conduced as a pilot study (44), a feasibility study (45) and an RCT (41, 46) which, however, was underpowered; and only one study has been conducted in people with advanced cancer (44). Thus, current evidence of occupation-focused and/or occupation-based interventions in people with advanced cancer is therefore scarce.

***Main results***

The efficacy of the 'Cancer Home-Life Intervention' turned out to be insignificant in terms of the chosen primary and seconday outcomes. The between-group difference in the ADL motor ability, which was the primary outcome, was -0.04 logits (95% CI: -0.23 to 0.15). The logit measures were therefore far from being either clinically relevant (0.3 logits) or statistically significant (see Table 2). Furthermore, no statistically significant effect was found in the explorative subgroup analyses; however, participants aged <69 years seemed to benefit more than those aged ≥69 years (0.30 logits [95% CI:-0.05 to 0.64], $p$=0.09). Gitlin et al. (79) also found a statistically significant differential age effect of an occupation-focused intervention on ADL ability in older adults. However, Gitlin et al. (79) found the opposite trend, i.e. that older individuals aged ≥80 had statistically significantly greater effect of the intervention than those aged <80 years, whereas the 'Cancer Home-Life Intervention' found that younger participants (<69 years) seemed to have the greatest effect. The included participants in the study by Gitlin et al. were all ≥70 years, and differential effects were therefore mainly compared amongst the oldest old participants (mean age=79 years). Furthermore, the two study poluations are not immediately comparable since people with advanced cancer are

living with a life-threatning disease and experience complex needs and problems (31, 76) that may vary over time (56). Some research in people with advanced cancer suggests that younger age is associated with higher risk of unmet needs in relation to ADL (86). Younger participants might therefore be more devoted to learning new strategies to overcome their difficulties performing ADL.

***Lenght and intensity of intervention***

Overall, lack of effect of more psychosocially oriented interventions in people with advanced cancer is not uncommon (80, 87, 88). For instance, Groenvold et al. (87) found no effect on EORTC symptom scales or function scales of early specialist palliative care in people with advanced cancer. The majority of the participants received only one face-to-face contact (87). This might indicate that people with advanced cancer may be too fragile to receive many face-to-face visits and illustrates the complexity of conducting intervention studies in this group of people. In continuation hereof, there may be some plausible explanations as to why the 'Cancer Home-Life Intervention' produced insignificant results. One of these may be the lack of adequate intervention intensity and duration. The 'Cancer Home-Life Intervention' was delivered during 3 weeks, mostly through a single home visit (median minutes=105) and a single follow-up telephone contact, even if participants were offered 1-3 home visits and 1-3 telephone contacts. The delivered intervention may therefore be characterise as being a low-intensity intervention (89). The intensity and duration of the 'Cancer Home-Life Intervention' may have been too low and/or too short (42, 50, 51), but some studies show that low-intensity interventions with short time of delivery can produce effect (43, 45, 89). Thus, it is debatable what constitutes the ideal length of an occupation-focused and/or occupation-based intervention.

A recent systematic review showed short-term effect of low-intensity occupation-focused and occupation-based interventions on ADL ability among older adults with different chronic diseases (90). The approaches of the occupation-focused and occupation-based interventions in the systematic review were often adaptive in the sense that they used various intrinsic and extrinsic adjustments, such as adaptation of occupations, providing assistive technology and home modification (90). The intervention components were thus similar to those used in the 'Cancer Home-Life Intervention'. The interventions were provided over a period of 2.5-6 months, and the mean intensity was 0.8-3.4 sessions per month (90). Thus, the 'Cancer Home-Life

Intervention' intensity was almost comparable to that of the intervention studies in the systematic review; yet, it was provided over a shorter period (90). The 'Cancer Home-Life Intervention' may hence have been provided over too short a period to change the participants' abilities to perform ADL and other kinds of occupations. On the other hand, in the telephone-delivered intervention by Hegel et al., two treatment sessions provided during 6 weeks were sufficient to instil a change in HRQoL, emotional state and function even though the study probably lacked statistical power (45). These results are in line with those of a previous exploratory RCT by Zingmark et al. who found that one 2-hour session of occupation-focused intervention was sufficient to achieve effect on ADL ability at 12 weeks of follow-up for older adults (43). So, it cannot necessarily be claimed that short interventions are not efficacious. However, one may question if 3 weeks was enough to install a change in ADL in people with advanced cancer. However, a longer time frame and/or a more demanding and intensive intervention may not be applicable for people with advanced-stage cancer who have limited time left and may become too ill to benefit from a more demanding intervention. Furthermore, they may also be at a stage in their disease trajectory where they prefer to devote their time and energy to other, more important issues and where conditions such as fragility may interfere with their wishes and priorities, making it difficult to provide intensive home-based interventions (91).

Collectively, the evidence presented in this section suggests that it is still uncertain what is the minimum intensity and duration required to instil change. Furthermore, interventions conducted over long periods may not be ideal for people with advanced cancer because they may be too demanding, probably leading to a larger drop-out rate.

***Timing of intervention***

Intervention timing and motivation are other issues that may explain why the 'Cancer Home-Life Intervention' revealed no statistically significant results. People with advanced cancer have a well-known disease trajectory with a reasonably high functional level over a longer period of time, but suddenly they experience functional decline. This sudden decline may last for weeks or months until they die (92). The disease trajectory of people with advanced cancer was not taken into consideration when the present RCT was designed. The 'Cancer Home-Life Intervention' may have been delivered in the period where most of the participants had a high functional level and therefore had less need and/or motivation for an occupation-focused and/or occupation-based intervention.

This may be seen in the baseline characteristics where 64 participants (26.6%) reported not having any problems performing their prioritised occupations (see Table 2 in Paper 2, page 7-8) and in the low drop-out rate (19.0%) (93). The ideal intervention timing may be at the onset of decline in function since this critical point in time may mark the beginning of a period where participants may expect to face problems performing their prioritised occupations (92). However, it may be difficult to deliver the intervention exactly at the point in time when people with advanced cancer begin to decline, particularly in a research study that rarely allows for this kind of flexibility. Furthermore, since the decline phase is short, participants may quickly become too ill to benefit from an occupation-focused and/or occupation-based intervention; indeed, they may also have other issues than occupations on their minds (91), such as where and how they want to die (94).

***Problems with occupations outside the home enviroment***

The 'Cancer Home-Life Intervention' intended to enable the participant-selected occupations at home. These occupations were mainly IADL tasks, such as cleaning, cooking and gardening (Figure 3). However, the ACQ cross-sectional study showed that the participants also had prioritised occupations outside their home environment, e.g. occupations like cycling and travelling (36). Some people with advanced cancer may feel that they are trapped in their homes, and this may be their main problem; not problems with cleaning and cooking which were the primary targets of the present intervention. In a qualitative study by Peoples et al., many of the participants talked about living a daily life that was restricted to their home environment which stood in constrast to their life before cancer struck where they lived a more active social life outside their home environment (95). For instance, a participant talked about using the internet to order groceries, which meant that he was still able to shop, but at the same time this increased his isolation at home (95). Although the 'Cancer Home-Life Intervention' was not supposed to target occupations outside the participant's home environment, the I-OTs still addressed problems with transportation and shopping during the interventions (see Figure 3). This may be problematic since the outcome instruments used in the present PhD project most likely were not able to capture this aspect. This may have diluted a possible effect of the 'Cancer Home-Life Intervention'. However, only a small amount of delivered interventions was targeted towards occupations outside the participant's home environment (see Figure 3). Nevertheless,

our findings highlight that people with advanced cancer have participant-selected occupations outside their home environment that also need to be addressed in palliative care interventions. It may have been useful to have expanded the context in which the 'Cancer Home-Life Intervention' was delivered so as to include not only the home environment but also the actual context in which occupations were performed, e.g. the supermarked if the selected occupation was shopping. On the other hand, the majority of people living with advanced cancer prefer to spend most of the remaining time of their life at home, (25, 26) where most of the ADL tasks also take place (96). Overall, it is debatable whether the 'Cancer Home-Life Intervention' was too narrow with regard to only selecting the home environment as the intervention context, but the aim of the intervention was to support people's daily life at home.

***Palliative rehabilitation***

Recent years have seen a growing focus on the conceptual relation between rehabilitation and palliative care in Denmark (21, 97). According to the World Health Organization (WHO), palliative care aims to improve HRQoL through prevention and relief of physical, psychological and spiritual problems (98). The WHO defines rehabilitation as an approach that supports people who experience or potentially will experience disability to achive and maintain optimal functioning (99). Palliative rehabilitation covers the integration of the two approaches and aims to enable people to live fully until the end of their life (100). Occupational therapy is one such approach to providing care in palliative rehabilitation, and it is mostly delivered in the context of basic palliative care (101, 102), and managed by the general practicitioners, the municipality and the non-specialised hospitals (103). Several RCTs are currently being conducted in Denmark evaluating the effect of a multidisciplinary, palliative rehabilitation intervention, also involving occupational therapy, in people with advanced cancer (104-106). Since people with advanced cancer represent a group with complex needs and problems (31, 76), palliative rehabilitation for this group may, indeed, call for a multidisciplinary intervention encompassing constributions from several health professions, e.g. physiotherapy (28). This accords with a recent report by the Danish Health Authority that also recommends a multidisciplinary intervention when delivering palliative services in Denmark (107).

***Methodological considerations***

The 'Cancer Home-Life Intervention' was evaluated by means of an RCT as this design is considered to be the golden standard when trying to explain causality, e.g. evaluating treatment efficacy (108). Randomisation often ensures comparable groups. Randomisation therefore minimises confounding, which is often a major weakness in other study designs; a weakness that interferes with their ability to say anything about causality (108). Still, there may also be methodological flaws in an RCT, e.g. insufficient power, large and unequal dropout between groups and lack of blinding of intervention providers, participants and those assessing outcomes (108). Given the nature of the 'Cancer Home-Life Intervention', it was not possible to blind either participants or the I-OTs. Nevertheless, the present RCT has several strenghts that need to be highlighted. Firstly, it was conducted rigorously with blinded outcome assessors (D-OTs) and successfully performed randomisation, and it reached the expected sample size. Secondly, there were no significant differences between included participants and those who declined participation with regard to age, gender, WHO PS and primary tumour. Thirdly, few and equal dropout rates were observed in the two groups during the 12 weeks of follow-up. The same tendency was found regarding missing values in the outcome measures (intervention: 15.3% [T2] and 2% [T3]) vs. control: 17.0% [T2] and 3.1% [T3]). Lastly, we used valid and reliable outcome instruments and decided to validate all AMPS data during the study period. This suggest, overall, that we have limited sources of error like selection bias and information bias, which thereby strengthens the internal validity of the study. Moreover, the subgroup analyses were performed as recommended with only the primary trial outcome (109) and using two of the most plausible moderators of treatment effect (age and gender) as interaction terms in the multiple linear regression model (79, 82). Although the present RCT was conducted rigorously and generally demonstrates strong internal validity, there may be other methodological issues that have influenced the results of the present PhD project.

*Inclusion criteria*

The included participants had a WHO PS score of 1 and 2 and were thus expected to face difficulties performing ADL tasks (110). The WHO PS plays a crucial role in cancer care in terms of predicting prognosis and deciding on appropriate treatment. Furthermore, the instrument is often used to include eligible patients in RCT studies (110). It assesses functional level, i.e. to which extent the patients are ambulatory and

how many hours they are bedridden. In the present RCT, two-thirds of the participants (71%) had a WHO PS score of 1. The patients with better functional level were therefore included (level 1 is better than level 2), which is also reflected in the low drop-out during the 12-week follow-up (19.0%) (93). According to the WHO PS, these patients are expected to have problems with their ADLs (110). The WHO PS is known to be a valid and reliable instrument able to predict treatment tolerability and survival in people with cancer (111, 112). However, the WHO PS may be too crude and imprecise an instrument to identify those patients who actually had problems with their ADLs since 64 participants (26.6%) reported having no problems with their occupations, including ADLs (see Table 2 in Paper 2, page 7-8). This might indicate that the present RCT has included some participants who had no need of an occupation-focused and occupation-based intervention. According to the AMPS, almost all participants (n = 230; 95.4%) had an observed ADL motor ability below the competence cut-off (3); i.e., their observed occupational performance indicated safety risk and/or need for assistance. This finding suggests that the relevant group of patients was included in the present RCT and confirms that WHO PS1 patients have problems with their ADLs. Nevertheless, in the 'Cancer Home-Life Intervention', the number of intervention components and number of home visits were delivered based on the participants' self-reported problems with their occupations. This may explain why only 36 participants (29.8%) in the intervention group received more than one home visit. Future occupation-focused and/or occupation-based interventions should use the WHO PS as a screening tool to identify relevant participants. However, it may be necessary to add another screening question addressing whether potential participants actually have problems with their occupations as this will most likely ensure that they need an occupation-focused and/or occupation-based intervention.

*Outcome instruments*

In the present RCT, the selected outcomes assessing people's occupations were based on both self-report and observation since previous studies show that using these methods produces different but complementary information (8, 9). Using these two methods also ensured that both the participant's and the OT's perspectives were represented. Outcomes based on self-report and observation should therefore be used in studies evaluating the efficacy of an occupation-focused and/or occupation-based intervention (8).

The AMPS was selected as the primary outcome since research shows that people with advanced cancer face difficulties performing ADL tasks (10, 11, 28-31) and that they report that staying independent is a high priority (29, 32-35). The AMPS is known to be more responsive to capturing changes than other common ADL instruments used in people with cancer (3, 113), which is an important feature when evaluating the efficacy of an intervention (114). The D-OTs were all newly calibrated AMPS raters, but several times they reported that they found it difficult to perform the AMPS, e.g. how to instruct the participants about the tasks they had to perform as part of the AMPS observation. Some participants reported to be uncomfortable when being assessed by the AMPS in their home environment. This illustrates the importance of providing the participants with thorough instruction prior to the AMPS observation, but also the importance of providing feedback. In the present PhD project, the participants were not given feedback after the AMPS observation as this may be considered a kind of intervention. Even though the D-OTs found the AMPS challenging, the instrument was feasible for people with advanced cancer, which can be seen in the low miss rate in the AMPS data.

The IPPA was used to assess the participants' self-reported occupational performance (63, 64). Some might have questioned the selection of the IPPA instead of the known and psychometrically well-tested occupational therapy measure, the Canadian Occupational Performance Measure (COPM) (115). The COPM is an instrument that supports clients in identifying and prioritising up to five occupations and afterwards in evaluating their self-reported experience performing these occupations (115). Like the IPPA, the COPM is a generic instrument. Thus, there is much similarity between the IPPA and the COPM. The IPPA was chosen since it was developed particularly to evaluate the effectiveness of an assistive technology provision (63, 64) and because it has been used as an outcome also in other RCTs (49). Among other intervention components, the 'Cancer Home-Life Intervention' also provided assistive technology. However, although being almost comparable instruments, the psychometric properties of the IPPA (62-64) are not so well researced as those of the COPM (115-122). Still, the IPPA is shown to be a responsive and valid instrument (63, 64). The choice of the IPPA instead of the COPM is therefore not considered be have influenced the results of the present RCT.

*Diluted effect*

Participants in both groups were assessed with the IPPA by a D-OT who interviewed them about their difficulties performing their prioritised occupations at home. It is important to recognise the potential effect of these interviews as conducting the interviews could have made the participants aware of their problems with their prioritised occupations and encouraged them to do something about it (93). Thus, it may be claimed that the control group also received some kind of intervention. This may have diluted the potential effect of the 'Cancer Home-Life Intervention', specifically on the IPPA, and produced bias towards the null value. This may be illustrated in the results where both groups reported statistically significantly fewer difficulties performing prioritised occupations assessed by the IPPA (see Table 2). On the other hand, the participants may have underestimated their true difficulties because they wanted to please the D-OTs and may also have wanted to positively contribute to show effect of the intervention. This is also known as the *Hawthorne effect* which is a well-known phenomenon in any RCT (108).

*Link between the intervention components and the outcomes*

Linking the intervention components to the outcomes may have profound importance as to ensure that an intervention will succeed in showing an effect (123). The causal connection between the intervention and the outcomes may also become clearer when trying to describe this link. Logic models have been developed to make this possible (123). However, in the development of the 'Cancer Home-Life Intervention', logic models were not used, wherefore the link between the components and the outcomes was undefined. This may also explain why the 'Cancer Home-Life Intervention' showed no effect. For instance, the AMPS only measured ADL ability, but the 'Cancer Home-Life Intervention' was broader in scope, targeting all kinds of participant-selected occupations within the participants' home environments, i.e. not exclusively ADL. This disconnection between the intervention and ADL could have negatively affected the causal connection, leading to insignificant findings in ADL motor ability and ADL aprocess ability. Furthermore, the prioritised occupations identified by the IPPA were not necessarily the same occupations that turned out to be the target of the 'Cancer Home-Life Intervention'. The participants could change their opinion about their occupations between the T1 visit and the first intervention visit as the I-OT started the intervention by conducting an initial interview allowing new occupations to be

identified. This means that the participants occasionally did not receive interventions targeting the occupations identified in the IPPA; expecting to find an effect may therefore be unrealistic as the participants scored difficulties performing only those occupations that were identified *a priori*. Devoting more effort to the development of the 'Cancer-Home-Life Intervention' would therefore have been preferable.

*Development and feasibility testning*

Occupation-focused and/or occupation-based interventions can be considered to be complex interventions as they often encompass several tailored, interacting components that require some kind of behavioural adaptation both by those providing and those receiving the intervention (124). The extent of the intervention delivered in the 'Cancer Home-Life Intervention', e.g. number of components, number of home visits and telephone contacts, was tailored to each individual participant. Overall, this tailoring, however, may make it difficult to evaluate what exactly caused or did not cause an effect (124). The 'Cancer Home-Life Intervention' was therefore difficult to evaluate since not all participants received the same components and the same number of contacts.

The Medical Research Council (MRC) presents a guideline on how to develop, pilot, evaluate and implement complex interventions (124). The development consists of three steps; 1) identifying exsisting evidence through a systematic review; 2) selecting a programme theory that can explain how the intervention intends to cause a change; 3) model process and outcomes. Once the intervention has been developed, the next step is to feasibility/pilot-test the intervention for acceptability, compliance and delivery. Another step is to collect information about recruitment and attrition rate and effect sizes, which can be used in the sample size calculation. The feasibility/pilot study should investigate all uncertainties that were identified during the development phase. The MRC guideline therefore emphasises the importance of investing enough effort in developing and piloting the intervention before a full-scale RCT is launched (124). The cross-sectional ACQ project study provided the present RCT with information about recruitment, procedures for data collection and empirical data on the variance of the ADL motor ability in people with advanced cancer, which was necessary for calculating the required sample size (36). Furthermore, the 'Cancer Home-Life Intervention' was tested in four people with advanced cancer. However, a feasibility study would have been preferable as this may have given indications about the number of home visits and

telephone contacts and the relevance of the intervention components for people with advanced cancer. Overall, not performing a regular feasibility study as recommended by the MRC guideline may be the most critical flaw and deficiency of the present RCT.

*Intervention fidelity*

The I-OTs took part in a 1-day workshop where they were calibrated to deliver the 'Cancer Home-Life Intervention'. Furthermore, in order to enhance the fidelity when delivering the intervention, three meetings were held during the study period. At these meetings, the I-OTs reported to use and follow the intervention manual (see Appendix A). However, sometimes they delivered interventions that were not in accord with the intervention manual. For example, the I-OTs delivered interventions targeted at occupations outside the participants' home environments, supported the intervention participants to engage in physical exercise and referred them to physical rehabilitation programmes offered by the municipality and the Danish Cancer Society (Figure 3). The discrepancy between the delivered interventions and the intervention manual were only minor. Still, this points towards the importance of performing a process evaluation that assesses fidelity and implementation of the 'Cancer Home-Life Intervention'. This is also in line with the MRC guideline (124). Such a study is currently in progress within the context of the ACQ project.

*Stratification into subgroups*

The MRC guideline also recommends evaluators to plan subgroup analyses as the effect may vary in subgroups of people (78, 124). The most appropiate way to investigate for subgroup effect is by performing an interaction test (125). Only age and gender were entered into the linear regression model as possible moderators of treatment effect. The remaining subgroups were not tested for interaction, but were analysed separately in a stratified analysis. However, by analysing the subgroups separately, the sample size is reduced which decreases the chance of obtaining a statistically significant result. Overall, these subgroup analyses are explorative and must be viewed as hypothesis generating as the randomisation is lost when stratifying the sample into subgroups. This could have been avoided if the stratification had been made before randomisation (125). A stratified randomisation using potential moderators as stratum groups would have been possible in the present RCT, but more participants should have been included to obtain the required power in each stratum(126). However, we faced severe problems

recruiting participants into the study, wherefore it had been difficult to include even more than the 242 participants whom we managed to recruit.

*Statistical analyses*

Parametric statistics were used to evaluate the efficacy of the 'Cancer Home-Life Intervention' on occupational performance (AMPS and IPPA) and HRQoL (EORTC) as these outcomes were considered to be quantitative measures. However, this way of treating data might raise critical concerns among some scholars. AMPS transforms ordinal data into interval data using the many-faceted Rasch measurement model. Interval data are characterised by having equal distance between each step on the scale (127). The AMPS can therefore be considered to be a quantitative outcome measure (3). Equal distance between scores may not be achieved when using the IPPA and the EORCT QLQ C-30. The IPPA is based on ordinal data; but according to the IPPA manual, data need to be calculated in order to obtain the total IPPA score ranging from 1-26. The HRQoL raw data are also ordinal and are linearly transformed into scores ranging from 0-100. A critical scholar might claim that these instruments cannot be analysed using parametric statistics since the distance between the scores might not be the same, which is prerequisite for treating data as quantitative measures (127). The analyses were performed using a more pragmatic approach, meaning that given the range of scores (IPPA=1-26 and EORCT=0-100) and in light of the sample size of the study population, a normal destribution was presumed suitable for describing the data, thus allowing the use of parametric statistics. I acknowledge that this does not completely fulfil all required assumptions for treating these data as quantitative measures. However, using parametric statistics is in accordance with the instrument manuals (62, 70) and is usually also what other studies do when analysing the IPPA and the EORTC (49, 63, 64, 87). Ideally, when data are exactly normally distributed, using parametric or non-parametric statistics will yield the same result as mean and median equals in a normal distribution. Since IPPA and EORTC data were normally distributed, the way in which data were treated is not considered to have influenced the results of the present RCT.

The IPA-DK uses an ordinal scale with scores ranging from 0-4 (65). It would therefore have been appropriate to have used ordinal logistic regression. Instead, the ordinal data were dichotomised into no perceived restrictions (score 0 and 1) and perceived restrictions (scores 2, 3 and 4). There were two reasons for doing so. First, it

may be more easy to interpret results from a logistic regression analysis than from an ordinal logistic analysis. Second, celling effect occured in the three domains of the IPA-DK (Autonomy indoors, Family role and Social relations) with scores of 0 and 1 being most frequently scored by the participants. Thus, dichotoming data was reasonable mainly because too few scores were observed in the individual reponse categories 2,3 and 4 of the IPA-DK.

Missing data is unavoidable in RCTs, and performing a strict intention-to-treat analysis is difficult (128). The Consort Statements recommend two methods in order to handle missing data (128): either simply just omit those participants with missing values in the outcomes or impute the missing values. When participants with missing values in the outcomes are omitted from the analysis, it is no longer possible to do intention-to-treat analysis (128). This kind of analysis is called a complete case analysis, which only includes those participants with known outcomes. In a complete case analysis, nobody else is excluded from the analyses, and the participants are analysed according to their original randomisation group. In the present RCT, the primary analyses were performed in a complete case analysis, and imputation was planned as sensitivity analyses (129). However, since few and equal drop-out were observed in the two groups and missing values in the outcome measures were few, imputations were not performed. In addition, the main reason for drop-out was death, where imputation is considered to be inappropriate as patient-reported outcomes are no longer relevant when people are dead (130).

*Conceptual framework in this thesis*

The present PhD project was written from an occupational therapy point of view, using Anne Fisher's conceptual framework. This was chosen mainly for two reasons; Firstly, the framework strongly emphasises the value of using occupation in relation to both intervention and evaluation (2). Secondly, in constrast to other known occupational therapy conceptual frameworks (131), Anne Fisher's framework is particularly clear as it explicitly describes how to use occupation as a main ingredient in the interventions (2). In the present PhD project, occupation was also used as a main ingredient in the 'Cancer Home-Life Intervention' as well as in some of the selected outcomes (AMPS and IPPA). The rationale of using both occupation in relation to intervention and evaluation is that the developers of the intervention were all OTs and were therefore guided by an occupation-centred approach (2), which most likely influenced the

composition of intervention components. Some may stress that changing terminology may cause problems interpreting the results of the intervention as the 'Cancer Home-Life Intervention' originally was not developed to be an occupation-focused and/or occupation-based intervention. This may also be illustrated by the fact that very few intervention components were occupation-based (see Table 1). However, I would argue that changing terminology is not critical for interpreting the results as there are many similarities between Anne Fisher's conceptual framework and the 'Cancer Home-Life Intervention', e.g. their use of occupation as a therapeutic means in the intervention (2). Furthermore, both in the present thesis and in the ACQ project, occupations and prioritised everyday activities were used synonymously to describe tasks that have meaning and/or purpose for the participants.

***External validity***

The findings of the present PhD project are valid for people with advanced cancer living at home. However, we mostly recruited people in the age range 52-78 years who had a WHO PS score of 1 and lived with a partner. It is therefore likely that the findings are valid mainly in this group of people.

Although the RCT is the strongest design to minimise bias, participants included in trials often encompass a selected group of people who do not necessarily represent the entire population of people living with advanced cancer. For instance, the better patients are typically also those who have energy and strength to participate in a demanding RCT with sequential follow-ups and several intervention sessions. The RCT design is therefore known to ensure high interval validity but often lacks strong external validity (108). However, the results from the present PhD project may be generalised to other groups of people with occupational performance problems similar to those of people with advanced cancer. These results can be used when developing new occupation-focused an occupation-based interventions.

Although people with advanced cancer are living with a life-threatening disease, they still value to be engaged in occupations (11, 12), wherefore palliative care also needs to focus on enabling the occupations of people with advanced cancer in order to support them to live their life as fully as possible.

# Conclusion and perspectives and future research

***Conclusion***

The overall objective of the study was to evaluate the efficacy of the 'Cancer Home-Life Intervention' and usual care compared with usual care alone on occupational performance, autonomy and participation and HRQoL in people with advanced cancer living at home. The study also set out to explore whether subgroups of people may have gained positive effect of the intervention on ADL motor ability at T3, the primary trial outcome. No differences were found between the intervention group and the control group with regard to ADL motor ability, ADL process ability, difficulties performing their prioritised occupations, autonomy and participation, and HRQoL. Furthermore, there were no effects of the intervention in the subgroups *age*, *gender*, *years of education*, *type of primary tumour*, *functional level* and *problems performing prioritised occupations*. A modifying effect of age and gender was not found, but some indications were seen that participants aged <69 years benefited more than those aged ≥69 years. Taken together, there was no evidence supporting the efficacy of the 'Cancer Home-Life Intervention'. Whilst the present PhD project was conducted rigorously and generally demonstrates strong internal validity, there may be significant flaws in the design of the intervention and challenges in the recruitment of patients that need to be taken into account before falsifying the beneficial constribution of an occupation-focused and occupation-based intervention in people with advanced cancer.

***Perspectives and future research***

The discussion raised several issues relevant to consider to explain why the 'Cancer Home-Life Intervention' showed insignificant results. These issues include recruiting relevant patients, appropriacy of intervention intensity, duration and timing of the intervention and the link between the intervention components and the outcomes. This illustrates that more research is needed to determine the efficacy of occupation-focused and/or occupation-based interventions for people with advanced cancer. Thus, at this point of time, the present PhD project will probably have more significance for the research society than for clinical practice. Still, the study may have awakened the attention of decision-makers and may hopefully make them more aware of the OTs' role in existing palliative care services for people with advanced cancer.

When the 'Cancer Home-Life Intervention' was delivered, minor things may not have been implemented as intended, as shown by some of the findings of the present PhD project. Thus, it may be important to conduct a process evaluation that more carefully investigates what was implemented and how (132). Considering that the 'Cancer Home-Life Intervention' was inefficient, a process evaluation is particularly important to investigate whether something went wrong in the delivery. As mentioned earlier in the discussion, a process evaluation is currently in progress that will inform the discussion of the delivery of the 'Cancer Home-Life Intervention'. Besides conducting a process evaluation, it may also be relevant to gain insight into how the participants experienced receiving the 'Cancer Home-Life Intervention' and whether they felt that the intervention made a difference for their daily life at home. Furthermore, evaluating a complex intervention like the 'Cancer Home-Life Intervention' may require investigating the efficacy of the 'Cancer Home-Life Intervention' components separately and in combination.

The present PhD project provides important knowledge into how to develop and evaluate occupation-focused and occupation-based interventions in people with advanced cancer that may serve as a base for future studies. Future studies should plan to conduct a feasibility study prior to testing an intervention in a full-scale RCT. When conducting future studies or developing or refining existing occupation-focused and occupation-based interventions, it is also suggested that this be done, among others:

- To identify the minimum intensity and duration of an occupation-focused and/or occupation-based intervention that will instil an effect.

- To identify the ideal intervention timing in the disease trajectory of people with advanced cancer.
- To identify whether future occupation-focused and/or occupation-based intervention also needs to address occupations outside the home environment, in particular more social and leisure-oriented occupations.

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# Appendixes

Appendix A: Intervention manual

Appendix B: Data-collection manuals

*Appendix A: Intervention manual*

# Interventionsmanual

## Bedre hverdag med kræft

*Aktivitet, kræft og livskvalitet i eget hjem*
(AKT-projektet)


Aarhus Universitetshospital
Odense Universitetshospital
Bedre hverdag med kræft - interventionen

Interventionen 'Bedre hverdag med kræft' er udviklet på baggrund af AKT tværsnitsdata, systematisk litteratursøgning og kliniske retningslinjer fra forskellige steder i verden.
Interventionen tilbydes deltagere i AKT-projektets randomiserede, kontrollerede undersøgelse (RCT) på Aarhus Universitetshospital og Odense Universitetshospital i projektperioden 2015-2016.

Denne manual indeholder en oversigt over problemer og behov hos mennesker med uhelbredelig kræft og beskrivelse af de enkelte interventionskomponenter og dertilhørende underkomponenter til gennemførelse af intervention *i deltagerens hjem* (matrikel).

Selve registreringen af interventionen skal udfyldes i interventionsskemaet og arkiveres.

Interventionen foregår indenfor 3 uger fra første besøg. Der udføres 1-3 besøg med mulighed for 1-3 opfølgende telefonsamtaler. Selve interventionen består af 6 komponenter:

1. Indledende samtale mellem interventionsergoterapeut og deltager vedrørende behov for hverdagsaktiviteter i eget hjem
2. Prioritering af aktiviteter, tid og ressourcer
3. Graduering af aktiviteter og indlæring af teknikker
4. Tilpasning af hensigtsmæssige hvile- og arbejdsstillinger
5. Hjælpemidler: tilpasning og instruktion i brug af hjælpemidler
6. Tilpasning af bolig

Interventionskomponent 1 (*Indledende samtale mellem interventionsergoterapeut og deltager vedrørende behov for hverdagsaktiviteter i eget hjem*) er obligatorisk, dvs. **skal** altid finde sted, idet den danner grundlag for de øvrige interventionskomponenter. De øvrige interventionskomponenter 2-6 kan derefter vælges efter behov, men alle komponenter **skal** altid vurderes ift. relevans.
Efter interventionskomponent 1 (indledende samtale), noteres plan for iværksættelse af interventioner.

Registrering af interventionskomponenter (og underkomponenter) skal ske under – eller umiddelbart efter – hvert besøg hos deltageren for at undgå fejlkilder i registreringen.

Tidsregistrering skal ske efter hvert besøg/telefonsamtale.

Husk at notere dit navn, sygehus samt deltagerens ID på forsiden af interventionsskemaet, inden interventionen påbegyndes.
Deltagerens ID-nr. skal i øvrigt noteres på samtlige sider i interventionsskemaet!

Inden besøget bør deltagerens hospitalsjournal tjekkes mhp at sikre, at deltageren ikke er indlagt (eller død), samt for at få nødvendig viden, der kan have afgørende karakter for interventionen, fx om deltageren lider af knogleskørhed.

OBS. Interventionsterapeuter kan kontakte visitator i deltagerens

kommune med henblik på visitering af pleje eller hjælpemidler/boligændringer. Der kan ikke lægges planer om genoptræning eller udarbejdelse af genoptræningsplan. Såfremt deltageren efterspørger anden type rehabilitering, end den, der ydes med interventionen 'Bedre hverdag med kræft', opfordres deltageren til at kontakte egen læge, hospitalsafdeling (hvortil deltageren er tilknyttet) eller visitator i kommune.

Ved tvivl om udfyldelse af interventionsskemaet, kontakt projektleder Åse Brandt (tlf. 41 74 00 19, aab@socialstyrelsen.dk).

## Problemer og behov hos personer med uhelbredelig kræft

AKT projektets tværsnitsstudie resultater viste, at over halvdelen deltagerne led af træthed, og næsten halvdelen havde følt sig svage, havde smerter, behov for hvile eller åndenød. Ca. halvdelen angav, at de havde nedsat mobilitet, og næsten lige så mange at de havde nedsat balance.

Når deltagerne selv angav deres ADL-evne ved hjælp af et struktureret interviewredskab, var det især tunge aktiviteter som rengøring, madlavning, tøjvask, indkøb og transport, de beskrev, at de havde problemer med. Der var færrest problemer med personlig ADL (P-ADL), undtaget fodpleje og at få sokker og sko på.

Aktiviteter i hverdagen, som deltagerne prioriterede at kunne være med i, og som de havde problemer med, blev undersøgt med et semistruktureret interview. Flest nævnte: *sociale relationer*, fx have gæster, tage på besøg, hjælpe familien, uformel kontakt til naboer, *skabende aktiviteter*, fx havearbejde, håndarbejde, håndværk, skrive, spille musik, og *oplevelser*, fx gå i byen, museum, restaurant, koncert, rejse, flyve, sidde i solen, gå en tur, nyde naturen.

Som svar på åbne spørgsmål gav mange deltagere udtryk for en sorg over ikke at kunne det, de havde kunnet tidligere, fx passe haven og dyrke sport. Desuden var der mange, der savnede mere kontakt med andre. Men nogle oplevede glæde ved at gøre det, de nu engang magtede.

Mange, som lever med en uhelbredelig kræftsygdom, oplever symptomer af både sygdommen og den behandling, som de modtager. Bilag 1 viser en liste over typiske symptomer, fordelt på kræftdiagnoser.

En undersøgelse[1] af kræftpatienters selvformulerede rehabiliteringsmål viste, at

- 56% var relateret til egenomsorg,
- 25% var relateret til fritidsaktiviteter og
- 19 % var relateret til arbejde og produktivitet.

[1] Lindahl-Jacobsen L. Occupational therapy for cancer patients – a randomised, controlled study. Research Unit of General Practice, Institute of Public Health. University of Southern Denmark, 2013. PhD thesis.

## Inden besøget

Inden første besøg er der en række dokumenter fra dataindsamlingen, som interventionsterapeuten skal gennemse og sætte sig ind i for at *tone* interventionen ud fra de behov og ønsker, deltagerne har givet indtryk for ved dataindsamlingen.
Det drejer sig om følgende dokumenter:

- IPPA (Individualized Prioritized Problems Analysis) (indikerer aktiviteter, som deltageren har problemer med og gerne vil kunne)
- Dagbogen (giver et overordnet indtryk af hvad deltageren laver i løbet af en dag)
- Hjælpemidler (angiver hvilke hjælpemidler deltageren har)
- Signifikante AMPS-færdigheder (viser hvilke færdigheder, der er påvirkede)
- Listen med de glædesskabende aktiviteter (centrale aktiviteter der skal gøres mulige)

## Ved besøgets start

Præsentér dig selv, din titel, samt at du er en del af AKT-projektet. Forbered deltageren på, at besøget vil være af max. to timers varighed og at det handler om, at gennemføre en indsats[2] relateret til hverdagen i hjemmet i samarbejde med deltageren.

[2] I manualen tales der om interventioner, men for mange af projektets deltagere vil dette fagsprog ikke sige dem noget, sig derfor "indsats", når du taler med projektdeltagere og deres pårørende.

Fortæl, at du, ved behov, vil lave et eller to ekstra besøg, samt at du, ligeledes ved behov, desuden vil foretage 1-3 telefoniske opfølgninger for at høre, hvordan det går med den indsats, deltageren har fået. Oplys deltageren om, at han/hun også kan ringe til dig, hvis der er brug for det. Indsatsen vil blive gennemført inden for tre uger efter det første besøg. Herefter betragtes forløbet som afsluttet og deltageren skal vide, at ved evt. behov i den efterfølgende periode skal de henvende sig til egen læge eller visitator i kommunen.

Inden du går til interventionskomponent 1 (indledende samtale mellem interventionsergoterapeut og deltager vedrørende behov for hverdagsaktiviteter i eget hjem), spørg da deltageren, om han/hun har nogle spørgsmål, inden I går i gang.

Når samtalen er afsluttet udfyldes et aftaleskema, hvor dine kontaktoplysninger findes, så deltageren kan huske, hvad der er aftalt og ved, hvor han/hun kan finde dit telefonnummer og komme i kontakt med dig.

## Interventionskomponent 1 – **obligatorisk**:

**1. Indledende samtale mellem interventionsergoterapeut og deltager vedrørende behov for hverdagsaktiviteter i eget hjem**

**Underkomponenter:**

1.A. Gennemgå daglige rutiner med deltageren (anvend dagbogsdata):
*Brug dagbogen som udgangspunkt. Denne del af undersøgelsen er en overordnet samtale, som skal medvirke til, at du får et indtryk af deltagerens aktiviteter og aktivitetsmønstre.*

*OBS: Optag på diktafon:*

*Start med at sige deltagerens ID-nr., dato og dit navn.*

*Tag afsæt i dagbogen, som deltageren har udfyldt til at gennemgå de daglige rutiner, som deltageren har i løbet af en typisk hverdag, sig fx:*

*- "I din dagbog kan jeg se at din dag går med at ...."*

*- "Hvordan fungerer de aktiviteter din dag består af herhjemme? Fx at lave mad, gøre rent/fodre fugle?" "Klarer du det selv?" "Hvordan fungerer det i forhold til din familie/samlever/roller – funktioner?"*

*- "Er den dag du har beskrevet, en typisk dag for dig?"*

*- "Er der nogle af dine aktiviteter i hverdagen, som er forandret, eller har fået ny betydning efter du har fået kræftsygdommen?" "Hvilke og hvordan?"*

*"Hvordan fungerer den måde du tilrettelægger hverdagen på?" "Når du det du gerne vil ?" (her kan spørges ind til fx rækkefølge, vaner, rutiner og prioritering af ressourcer).*

*Herefter afsluttes optagelsen!*

1.B. Adressere behov identificeret ud fra baseline-undersøgelsen:
*(Anvend resultater fra Dagbog, AMPS effektive og ikke effektive færdigheder, IPPA, IPA-DK og glædesskabende aktiviteter efter relevans) og adressér de områder, hvor deltageren har rapporteret uopfyldte behov eller områder, hvor deltageren ikke har mulighed for, på tilfredsstillende vis, at udføre en eller flere aktiviteter.*

*Spørg ind til behov og bed fx deltageren om at forklare, hvad der er svært, og hvad det betyder, at behov(ene) ikke bliver opfyldt.*
Sikre, at der spørges ind til dimensionerne (i hjemmet/på matriklen):
*- aktiviteter i relation til personlig pleje (fx bad, påklædning)*
*- huslige aktiviteter (fx rengøring, madlavning)*
*- hobby-aktiviteter (fx læse, se TV)*
*- interesser (fx sy, reparere ting, sport, fritid)*
*- sociale aktiviteter (fx familie, venner)*
*- glædesskabende aktiviteter (fx aktiviteter, som har en legende eller skabende karakter)*

***OBS: Brug Aktivitetstjeklisten (bilag 2) til at få et bredt indtryk af aktivitetsbehov. Det er vigtigt, at der er deltageren selv, der definerer behov.***

*Spørg desuden deltageren, om der er tilkommet noget nyt, siden dataindsamleren har været på besøg. Lad deltageren tænke lidt over det og*

*uddyb evt. med at spørge, om deltageren har oplevet noget i mellemtiden, som har haft betydning for hverdagen i hjemmet.*

1.C. Sikre, at der er tale om væsentlige og/eller relevante behov for deltageren:
*Når du taler med deltageren, så sikre dig, at de behov, som deltageren kommer med, er relevante og/eller væsentlige.*
*Spørg fx indtil:*

- *hvorfor aktiviteterne er vigtige*
- *hvad aktiviteter(ne) betyder for deltageren*
- *om det er aktiviteter, deltageren er vant til at være ansvarlig for*
- *om aktiviteterne har betydning for deltagerens velvære*
- *om aktiviteterne har betydning for deltagerens selvfølelse*
- *om det er aktiviteter, som deltageren oplever glæde ved at udføre*

1.D. Spørg ind til, om deltageren oplever følgende symptomer:
*- Træthed*
*- Smerter*
*- Hævelser*
*- Føleforstyrrelser*
*- Besværet vejrtrækning*
*- Uklar i hovedet*

1. E. Vurder, om der er aktivitets barrierer i boligen i/ved
*Når du går rundt sammen med deltageren i hjemmet inkl. de umiddelbart nære omgivelser, så læg mærke til, om der er fysiske barrierer i omgivelserne, der kan begrænse deltagerens aktivitetsudførelse. De kan fx bestå i, at der er trapper, der mangler greb at holde fast i, at ting er placeret, så de er vanskelige at nå, at der er for store afstande, m.v. Tjek hele boligen og tilstødende arealer:*
*- Indgangsparti og entre*
*- Stue(r)*
*- Køkken, grovkøkken*
*- Badeværelse*
*- Soveværelse*
*- Vaskerum*
*- Postkasse*
*- Affaldsaflevering*
*- Garage*
*- Have*

1.F. Vurder, om hjemmet er sikkert i forhold til aktivitetsudøvelse
*Under gennemgangen af boligen vurderes det, om der er sikkerhedsrisici ved aktivitetsudførelse, fx fald, at deltageren på grund af kognitiv funktionsnedsættelse glemmer at slukke for komfur, der er tæpper og dørtrin, deltageren kan falde over, m.v.*

**Notater:**
*Fx deltagerens humør og særlige omstændigheder*
*Hvis det virker som om deltagerens humør er dårligt, deltageren virker nedtrykt, der er sket negative begivenheder der kan påvirker deltageren, o.lign. noteres det her.*

**Plan for iværksættelse af indsatser:**
*Brug de informationer du har fået fra deltageren under komponent 1 til at overveje, hvilke(n) type(r) interventionskomponent(er), der skal tages i brug i interventionen. Nedskriv dette, så en kollega kan overtage efter dig, hvis det skulle blive nødvendigt.*

# Interventionskomponent 2 – kan vælges:

**2. Prioritering af aktiviteter, tid og ressourcer**

**Underkomponenter:**
2.A. Med udgangspunkt i typisk hverdag assistere deltageren i at prioritere i aktiviteter, tid og ressourcer, herunder inddrage:
- planlægning: *her spørges ind til om dagene planlægges bevidst og om, hvad der er styrende for, hvordan dagene forløber, såsom behandlinger, praktiske gøremål som indkøb o.lign.*
- prioritering: *tal med deltageren om, hvordan aktiviteter og tid prioriteres og om og hvordan der kan omprioriteres, så fx vigtige glædesskabende aktiviteter får mere tid frem for aktiviteter som tager på kræfterne. Hvordan kan deltageren vægte de væsentlige aktiviteter? Hvis en vigtig aktivitet er fysisk træning i hjemmet, kan der gives instruktioner i hvordan det kan gøres.*
- gøre glædesskabende aktiviteter mulige: *her kan tales med deltagerne om, hvordan deltageren kan fokusere på netop de aktiviteter, der giver glæde i hverdagen*
- afslapning/fysisk besvær: *tal med deltageren om, hvordan pauser og hvile integreres ind i løbet af dagen, fx om der skal ændres i mønstret så pauserne kommer inden udtrætning (tager udtrætning i opløbet)*

2.B. Assistere deltageren i at tilrettelægge tiden, så der bliver mulighed for de ønskede aktiviteter:
*På baggrund af deltagerens udsagn ovenfor, drøftes væsentlige/relevante aktiviteter og løsningsmuligheder for at planlægge anderledes med henblik på at skabe plads til de aktiviteter, der er vigtigst for deltageren. Her er det vigtigt, at der fokuseres på de for deltageren væsentlige og glædesskabende aktiviteter. Løsningsmuligheder kan fx være at der flyttes rundt på aktiviteters placering, så fx bad ligger senere på dagen. Dagbogen kan eventuelt anvendes, så det bliver synligt for deltageren, hvilke aktiviteter der fylder mest.*

2.C. Analysere hvilke krav der skal til for at opfylde deltagerens aktivitetsbehov og håndtere evt. omgivelsesmæssige barrierer:
*I forlængelse af ovenstående analyseres, hvad der skal til af omgivelsesmæssige faktorer, for at muliggøre de aktiviteter, der er vigtigst for deltageren. Løsningsmuligheder kan fx være: at aktiviteter klares af andre (familiemedlemmer, hjemmehjælp, andre), der gives afkald på aktiviteter (så der skabes mulighed for at væsentlige aktiviteter opprioriteres). Der kan være behov for praktiske foranstaltninger og ændringer af døgnrytme, samt evt. aftaler med familiemedlemmer eller andre, som kan være nyttige at lave aftaler med for at sikre, at deltagerens behov imødekommes.*
*Såfremt der er behov for hjælpemidler, bør interventionskomponent 5 (hjælpemidler, tilpasning og instruktion i brug af hjælpemidler) komme i betragtning, og såfremt der er behov for boligændringer, bør interventionskomponent 6 (tilpasning af bolig) komme i betragtning.*

# Interventionskomponent 3 – kan vælges:

**3. Graduering af aktiviteter og indlæring af teknikker**

*Hvis interventionskomponent 2 (prioritering af aktiviteter, tid og ressourcer) har været anvendt, kan der bygges videre på den under denne komponent. Gradueringen kan så anvendes på de aktiviteter, som deltageren har opprioriteret.*

*Der kan være behov for, at deltageren modificerer sine egne krav til vaner og/eller behov. Der kan afprøves nye arbejdsrutiner og aktivitetsmønstre kan diskuteres. Det er vigtigt, at der fokuseres på deltagerens eksisterende evner.*

**Underkomponenter:**

3.A. Indlæring af teknikker, der skal hjælpe deltageren til at tilpasse sig sine ønsker/behov i relation til:

*- personlig pleje: Fx arbejde siddende frem for stående, dele opgaver op i del-elementer*
*- huslige opgaver: Fx dele opgaver op i del-elementer, ændre rækkefølge*
*- hobby-aktiviteter: Fx arbejde siddende frem for stående*
*- interesser: Fx dele opgaver op i del-elementer, ændre rækkefølge*
*- sociale roller: Ændre på ansvarsfordeling, bede om hjælp, fragive ansvar og få nyt ansvar*
*- glædesskabende aktiviteter: Lad være med at gøre andre ting, så der er kræfter tilbage.*

3.B. Graduere ønskede aktiviteter under hensyntagen til smerter og udtalt træthed (fatigue), fx indlægge pauser:
*Hvis der er smerter, kan det være nyttigt at tale om, hvordan aktiviteter kan udføres under hensyntagen til smerterne.*
*Hvis der er fatigue (abnorm træthed) kan det ligeledes være nyttigt at drøfte, hvordan der kan lægges pauser ind i aktiviteterne.*

*Hvis det synes oplagt, at der vælges kompensatoriske strategier, bør interventionskomponent 5 (hjælpemidler: tilpasning og instruktion i brug af hjælpemidler) komme i betragtning.*

# Interventionskomponent 4 – kan vælges:

**4. Tilpasning af hensigtsmæssige hvile- og arbejdsstillinger**

**Underkomponenter:**
4.A. Rådgivning/instruktion af deltager i forhold til:
*- Aktivitetsstillinger: Informér om og anvis ift deltagerens muligheder i hjemmet, hvordan en god siddende-stående stilling opnås. Informér om gavn af skiftende aktivitetsstillinger. Hvis deltageren har – eller er i risiko for at få – tryksår, informeres om, hvordan der tages hensyn til dette. Ved behov for hjælpemidler til at afhjælpe tryksår, bør interventionskomponent 5 (udlevering, tilpasning og instruktion i brug af hjælpemidler) komme i betragtning.*
*- Hvilestillinger: Informér om og anvis, hvordan deltageren kan opnå en god hvile-/liggestilling i seng eller andre steder, hvor han/hun hviler sig, hvis dette volder problemer for deltageren. Lejringsprincipper kan anvendes.*
*- Forflytning: Hvis forflytninger volder problemer, gives vejledning til deltager/pårørende om dette. Forflytninger kan både være små forflytninger, fx mellem stol/toilet og større forflytninger, som fx gang indendørs/i haven.*
*- Afslapningsstrategier: Informér om afslapningsstrategier fx afslapning/hvile/pause imellem aktiviteter. Informér om vigtigheden af at spare energi og sprede aktiviteter over tid, så man ikke udtrættes for hurtigt.*
*- Ergonomi (herunder holdning): Informér om og demonstrér for deltageren, hvordan der kan passes på kroppen i forbindelse med aktivitetsudførelse. Løft, gentagelse af arbejdsprocesser og andre ting, der kan være belastende for kroppen, kan med fordel gennemgås med deltageren med henblik på at øge fokus på, hvordan deltageren kan passe på sin krop og bedre muligheder for aktivitet. Her kan fx indgå ledbeskyttelse, vægtstangsprincippet, løfteteknik.*

4.B. Assistere deltageren i at skabe steder, hvor der kan opnås hvile i løbet af dagen:
*Helt konkret kan der være behov for, at deltageren får gode råd til valg af hvilesteder og hvilestillinger. Der kan fx indrettes en god stol – eller gerne flere – hvor deltageren kan hvile sig i løbet af dagen.*
*Der kan være behov for at indrette sengen med henblik på bedre hvile om natten. Bedre hvile kan have positiv indvirkning på smerter og vejrtrækning, hvilket kan have positiv indvirkning på aktivitetsudførelse i løbet af dagen.*

# Interventionskomponent 5 – kan vælges:

**5. Hjælpemidler: tilpasning og instruktion i brug af hjælpemidler**

**Underkomponenter:**
5.A. Hjælpemidler eller anden teknologi til understøttelse af deltagerens aktivitetsbehov

*Et overblik over hjælpemidler på det danske marked findes på Hjælpemiddelbasen, http://www.hmi-basen.dk/*

*Eksempler på hjælpemidler er:*

**Mobilitet**
- Stok
- Rollator
- Manuel kørestol
- Elkørestol/elscooter
- Rampe (inkl. lille rampe over dørtrin)
- Gelænder eller støttegreb ved trappe

**Personlig pleje**
- Indstillelig seng, evt. med el
- Lift/personløfter
- Tilkaldesystem
- Toiletforhøjer
- Badetaburet eller badesæde
- Bade- eller toiletstol
- Støttegreb, toiletstøtter
- Pilleudtrykker, badesvamp på skaft, gribetang eller andre mindre hjælpemidler
- Påklædningshjælpemiddel (fx strømpepåtager, skohorn)

**Husholdning**
- Arbejdsstol
- Køkkenhjælpemidler (fx køkkenmaskine, særlige kartoffelskræller)
- Rullebord
- Vandhanegreb
- Spisehjælpemidler
- Forhøjerklodser til stole og senge

**Kommunikation og rekreation**
- Hvilestol
- Kommunikationshjælpemiddel (fx taleforstærker, luplampe)
- Saks eller skriveredskab med forstørret greb o. lign.

Vurder først, hvilke hjælpemidler der kan være relevante, hvorefter deltageren involveres i beslutningen om, hvilke hjælpemidler, der kan være relevante.

Hvis der er mulighed for at ansøge om hjælpemidlet hos kommunen (servicelovens §112) gøres dette.

For at få et hjælpemiddel bevilget, skal
- borgeren have en varig nedsat funktionsevne og hjælpemidlet skal i væsentlig grad kunne afhjælpe de varige følger af den nedsatte funktionsevne
- hjælpemidlet i væsentlig grad kunne lette den daglige tilværelse i hjemmet
- hjælpemidlet ikke være almindeligt indbo (fx køkkenmaskine)
- hjælpemidlet ikke være forbrugsgode (servicelovens §113), dvs. et produkt, der kan købes i almindelige forretninger, og ikke er særligt fremstillet for at afhjælpe en funktionsnedsættelse, fx elevationsbund i seng. I disse

tilfælde kan ansøges om tilskud på halvdelen af anskaffelsesprisen (fastsat af kommunen).

*OBS: Kommunen giver ikke støtte til hjælpemidler, der er anskaffet.*

*Hvis der ikke er mulighed for at få hjælpemidlet bevilget af kommunen, indkøber AKT projektet hjælpemidlet (opgiv hjælpemidlets HMI-nummer, det findes i Hjælpemiddelbasen).*

*Hvis hjælpemidlet koster over 500 kr. eller hvis der er behov for tilpasninger kontaktes projektleder Åse Brandt: tlf. 41 74 00 19, aab@socialstyrelsen.dk). På Aarhus Universitetshospital udleveres hjælpemidlet fra hospitalets depot, og der gives besked til Åse Brandt om at indkøbe et nyt identisk hjælpemiddel til hospitalet. Hvis hjælpemidlet ikke findes på depotet, gives besked til Åse Brandt om indkøb af det med besked om, hvor hjælpemidlet skal sendes hen. På OUH følges sidstnævnte procedure.*

5.B. Instruktion i anvendelse af hjælpemidlet/hjælpemidlerne:
*Ved andet besøg afprøves hjælpemidlet, og deltageren instrueres i at anvende det til at udføre de(n) ønskede aktivitet(er). Instruktionen finder sted ved, at deltageren udfører de aktiviteter, som deltageren skal bruge hjælpemidlet til at udføre, i de omgivelser hvor de sædvanligvis finder sted.*

5.C. Vurdering af behov for boligændringer i forbindelse med hjælpemiddeludlevering:
*Det vurderes, om der er behov for boligændringer, for at hjælpemidlet kan anvendes, typisk i forbindelse med mobilitetshjælpemidler, fx fjernelse af dørtrin eller installation af små dørtrinsramper, så en rollator eller kørestol kan komme over dørtrinnene. Hvis dette er tilfældet, bør interventionskomponent 6 (tilpasning af bolig) komme i betragtning.*

5.D. Telefonisk opfølgning:
*Det følges telefonisk op, om hjælpemidlet fungerer efter hensigten. Hvis ikke, overvejes det hvordan problemet løses.*

## Interventionskomponent 6 – kan vælges:

**6. Tilpasning af boligen – omgivelsesmæssige barrierer og sikkerhed**

**Underkomponenter:**
6.A. Ændring af omgivelsesmæssige barrierer.
*På baggrund af vurderingen i komponent 1 om omgivelsesmæssige barrierer i hjemmet fokuseres på ændring af disse. Sammen med deltageren gennemgås de behov for ændringer af hjemmet, der blev fundet ved gennemgangen under interventionskomponent 1. Ændringerne kan bestå i at fjerne barrierer som fx at fjerne dørtrin, ændre barrierer ved fx at gøre det muligt for deltageren at sidde ned ved køkkenarbejde eller ved at kompensere for barrieren ved fx ved at sætte en rampe op, så deltageren kan komme ind i huset med rollator eller sætte et gelænder op, så deltageren kan støtte sig til den og derved klare trapperne. Der kan fx være tale om:*

- Opsætning af rampe, fx for at komme ind i boligen med

kørestol, komme over dørtrin med rollator eller kørestol
- Opsætning af støttegreb, fx ved trappetrin, toilet, brusebad
- Opsætning af gelænder, så det er lettere og sikrere at komme op og ned ad trapper
- Fjernelse af dørtrin for at komme rundt i boligen med rollator eller kørestol
- Fjernelse af badekar/ændring af brusebad, så det er muligt og sikkert at tage bad
- Skridsikker gulvbelægning i badeværelse
- Forhøjelse af toilet, så det er lettere at rejse sig
- Ændring af køkkenbord, så det fx er muligt at sidde ned og arbejde
- Ny belægning udendørs, så det er sikkert at komme rundt

6.B. Sikre at hjemmet er sikkert i forhold til aktivitetsudøvelse.
*Ved gennemgangen i komponent 1 blev det sammen med deltageren observeret, om det er sikkert for deltageren at udføre hverdagens aktiviteter.*

*Hvis der er risiko for ulykker, aftales med deltageren, hvad der skal gøres. Det kan være egentlige boligændringer (se eksempler under 6.B) eller ommøbleringer som fjernelse af løse tæpper, placering af møbler, så det er muligt at støtte sig til dem, m.v.*

6.A og 6.B: Hvis der er mulighed for at ansøge om boligændringen hos kommunen (servicelovens §116) gøres dette.

*For at få støtte til en boligændring skal ansøgeren have en varigt nedsat fysisk eller psykisk funktionsevne, og boligændringen (i lovgivningen kaldes det boligindretning) skal være nødvendig for at gøre boligen bedre egnet som opholdssted for den pågældende.*

*Kontakt evt. kommunen for at høre om mulighed for at få støtte, før der indsendes ansøgning (eller se kommunens hjemmeside), fx giver mange kommuner ikke længere støtte til etablering af bademulighed, støttegreb, osv.*

*OBS: Kommunen giver ikke støtte til boligændringer, der er foretaget.*

6.C. Ommøblering, omplacering af huskeråd m.v.:
*Observer om omgivelserne er hensigtsmæssigt indrettet i forhold til udførelse af hverdagens aktiviteter. Kan ting placeres mere hensigtsmæssigt, fx er placering af ting i over- og underskabe ofte uhensigtsmæssigt, eller ting er placeret ulogisk i forhold til den måde, aktiviteten udføres mest effektiv på. Det kan også være hensigtsmæssigt at flytte rundt på møbler, så det er lettere at færdes. Foreslå deltageren at flytte rundt på ting og afprøv den ændrede opstilling af ting.*

6.D. Telefonisk opfølgning:
*Det følges telefonisk op, om en evt. boligændring fungerer efter hensigten. Hvis ikke, overvejes det hvordan problemet løses.*

*OBS: I tilfælde af at deltagerens kommune ikke vil bevilge en foreslået boligændring, tages kontakt til projektleder Åse Brandt (tlf. 41 74 0019, aab@socialstyrelsen.dk).*

*Opsætning af støttegreb: Hvis muligt, udføres dette af familie/bekendte. Hvis dette ikke er tilfældet, kontaktes en tømrer. Interventionsergoterapeuten opsætter klistermærker, der viser, hvor støttegrebet skal opsættes. Kontakt Åse Brandt med henblik på elektronisk fakturering.*

## Ved afslutning af besøg:

**Ved afslutning af første besøg:**
Der udfyldes et aftaleskema, hvor der står, hvilke indsatser, der er aftalt. Deltageren får aftaleskemaet ved besøgets afslutning. På skemaet står interventionsterapeutens kontaktoplysninger, så deltageren eller pårørende kan kontakte terapeuten, hvis der skulle blive behov for det. Oplys, at der kan lægges besked med oplysning om navn og telefonnummer og at du vil ringe tilbage.

Der laves evt. aftale om andet besøg. Sørg for, at drøfte, hvornår det passer deltageren bedst. Fx
kan dagene umiddelbart efter kemoterapi er givet, være dårlige dage at lægge interventionen på.

Hvis der er behov for opfølgende telefonopkald, aftales hvornår dette foretages.

**Ved afslutning af (evt.) andet besøg:**
Der laves evt. aftale om tredje besøg. Sørg igen for at drøfte, hvornår det passer deltageren bedst.

**Ved afslutning på (evt.) tredje besøg:**
Hvis der er behov for opfølgende telefonopkald, aftales hvornår dette foretages.

## Registrering af kontakt mellem interventionsergoterapeut og deltager:

**Registrering af første og evt. andet og tredje besøg i hjemmet:**
*Det er, som nævnt i indledningen, vigtigt, at der føres eksakt registrering af alt, hvad der foretages i interventionen. Det er derfor også vigtigt, at det registreres, hvornår første og evt. andet og tredje besøg er foregået.*

**Registrering af opfølgende telefonsamtaler:**
*Derudover er det vigtigt, at det registreres, hvis (og i så fald hvornår) opfølgende telefonsamtale 1-3 har fundet sted, samt hvad der er vendt under disse samtaler. Såfremt der har været yderligere telefonsamtaler (hvis fx deltageren har henvendt sig pr. telefon), skal dette også registreres i interventionsskemaet.*

**Efter hvert besøg, registreres, hvor meget tid, der er anvendt på besøget.**

# Bilag 1. Typiske symptomer fordelt på kræftdiagnoser[3]

*Kvinder med brystkræft:*

- 66% betydelig træthed og hedeture
- 50% smerter
- 33% hævelse af arm/lymfødem

*Patienter med lungekræft:*

- 80% træthed
- 66% åndenød

*Patienter med tarmkræft:*

- 66% betydelig træthed
- 40 % fordøjelsesproblemer

*Patienter med prostatakræft:*

- 66% seksuelle problemer
- 40% vandladningsproblemer

*Kvinder med underlivskræft:*

- 66% betydelig træthed
- 50% søvnforstyrrelser
- 40% seksuelle problemer

[3] Høybye MT et al. Research in Danish cancer rehabilitation: social characteristics and late effects of cancer among participants in the FOCARE research project. Acta Oncologica 2008; 47(1):47-55.

# Bilag 2. Aktivitetstjekliste (fra IPPA)

*Denne liste kan bruges som inspiration til samtale om hvilke aktiviteter, deltageren udfører eller mangler at kunne udføre i hverdagen.*

**Omsorg for sig selv**
- Tage brusebad/bad/vaske sig
- Tand-/hår-/hud-/fodpleje
- Tage tøj af og på
- Spise/drikke
- Toiletbesøg
- Sove og hvile
- Tage vare på eget helbred, fx tage medicin, lave øvelser

**Mobilitet**
- Bevæge sig rundt inde/ude (gående, med kørestol eller andet hjælpemiddel)
- Gå på trapper
- Sætte og rejse sig fra stol
- Komme i og ud af sengen
- Seksualitet/intimt samvær
- Komme ind og ud af bil

**Huslige gøremål**
- Lave mad/forberede et måltid
- Gøre rent/vaske op
- Vaske/ordne tøj
- Købe ind
- Hente post
- Løfte ting/samle ting op
- Lettere reparationer
- Passe husholdningens regnskab/økonomi

**Sikkerhed**
- Alarmere ved brand
- Låse/låse yderdøre op
- Tilkalde hjælp

**Fritid**
- Se tv
- Høre radio/musik
- Læse avis/blade/bøger
- Slappe af
- Passe have
- Lege
- Bruge computer
- Spille
- Hobby
- Sport

**Kommunikation**
- Tale med andre (tale, høre, forstå)
- Benytte en telefon
- Læse/skrive

**Arbejde/studier i hjemmet**
- Arbejde
- Studier
- Frivilligt arbejde

**Social kontakt**
- Deltage i foreninger/organisationer hjemmefra
- Få besøg af familie/venner

*Appendix B: Data-collection manuals*

# Dataindsamlingsmanual – T1 baseline

**Huskeliste inden besøget**

Inden besøget skal du medtage følgende materialer:

- To eksemplarer af samtykkeerklæringen
- Papir til at tage notater
- Diktafon
- Syv eksemplarer af IPPA-scoringsark og IPPA aktivitetstjekliste
- To eksemplarer af AMPS-scoringsark
- Listen med de glædesskabende aktiviteter
- Listen med registrering af hjælpemidler T1
- Listen med registrering af boligændringer T1
- Skemaet "Kemobehandling T1"
- Listen med AMPS færdigheder
- Husk frimærker og en kuvert, som kan bruges til at sende dagbogen retur, hvis deltageren har glemt at udfylde den.
- Husk AMPS-manualen
- T1 spørgeskemaet

**Manualen**

Manualen beskriver den rækkefølge de forskellige undersøgelsesredskaber skal anvendes i, samt giver forslag til indledning.

Det er vigtigt at give projektdeltageren god tid.

**Oversigt over forløbet**

1. Introduktion
2. Samtykkeerklæring
3. Spørgeskemaer (EORTC-QLQ C-30, IPA-DK mv. samt dagbog)
4. Kemobehandling
5. Indledning til undersøgelserne og kvalitativt spørgsmål
6. IPPA
7. AMPS
8. Glædesskabende aktiviteter
9. Registrering af hjælpemidler og boligændringer
10. Aftale næste opfølgningsdato
11. Efter besøget

**Ad. 1. Introduktion**

**1.1 Præsenter dig selv og derefter projektet ganske kort**

Du skal starte med at præsentere dig selv. Herefter skal du fortælle følgende til projektdeltageren:

- Formålet med projektet er undersøge effekten af forskellige indsatser, der skal hjælpe mennesker med kræft til bedre at klare hverdagens aktiviteter i eget hjem.

- Formålet med dagens besøg er dels, at jeg skal interviewe dig om, hvilke problemstillinger du har med at udføre hverdagens aktiviteter i hjemmet og dels at observere dig, når du udfører et par hverdagsopgaver i dine hjemlige omgivelser.

- Der vil være ét besøg mere, hvor jeg vil stille de samme spørgsmål igen og observere dig i to hverdagsopgaver i hjemmet. Hensigten med det opfølgende besøg er at finde ud af, hvordan du klarer hverdagens aktiviteter over tid.

**Ad. 2. Samtykkeerklæring**

Du skal gennemgå samtykkeerklæring, indhente underskrift og udlevere kopi til projektdeltageren.

**Ad. 3. Spørgeskemaer og dagbog**

Du skal bede om de udsendte materialer. Hvis spørgeskemaet ikke er udfyldt, skal du udfylde det sammen med deltageren. Du skal spørge, om der har været problemer med at udfylde spørgeskema og/eller dagbog. **Check at alt er udfyldt**. Mangler der svar på enkelte spørgsmål kan disse afklares og udfyldes med projektdeltageren. Hvis deltageren ikke kan svare på et spørgsmål fra IPA-dk, der er i spørgeskemaet, skal deltageren beskrive årsagen i de kvalitative spørgsmål, som afslutter hver delområde i IPA-DK. Hvis deltageren ikke har lyst eller kan svare på IPA-DK spørgsmål 8e, 6, kan det bare undlades.

**Ad. 4. Kemobehandling**

4.1. Skemaet **"Kemobehandling T1"** udfyldes (vedlagt)

**Ad. 5. Indledning til undersøgelserne og kvalitativt spørgsmål**

Introducer først, at du gerne vil vide noget om, hvordan hverdagen fungerer i hjemmet;

*"Vi taler først lidt om hverdagens aktiviteter i dit hjem. Derefter vil jeg gerne se dig udføre to opgaver, som er relevante for din hverdag". "Herefter skal jeg registrere, hvilke hjælpemidler du har og om der er foretaget boligændringer i dit hjem".*

*OBS: Optag med diktafon: Start med at sige deltagerens ID-nr., dato, dit navn og at det er T1.*

*Du skal spørge om følgende (Det er vigtigt, at deltageren får god tid til at svare):*

- Hvordan klarer du hverdagen og dens gøremål?

Stop optagelse med diktafon

**Ad. 6. IPPA**

- Du skal udføre interviewet efter retningslinjerne – se manual – med undtagelse af at du skal afgrænse spørgsmålene til aktiviteter, der **foregår i hjemmet**: "Fortæl om de daglige gøremål eller opgaver i hverdagen her i dit hjem, som du har svært ved eller ikke kan klare". Når deltagerne skal score, skal de tage udgangspunkt i den dag, hvor interviewet foregår, og hvis de ikke har udført aktiviteten den dag, så ud fra den seneste gang, de udførte aktiviteten.
- Hvis der ikke bliver identificeret aktivitetsproblemer i IPPA-interviewet, skal man ikke presse deltageren, men blot skrive "0" på IPPA-scoringsark.

**Ad. 7. AMPS observation**

- Du skal udføre testen efter retningslinjerne – se manual. Med baggrund i IPPA og deltagernes dagbog skal du Indlede et AMPS-interview mhp. at identificere to relevante ADL-opgaver. Det er **vigtigt**, at de to opgaver har en **passende sværhedsgrad** (ved næste besøg kan det være de samme eller andre aktiviteter).

- Hvis du ikke kan AMPS-teste deltageren ved hjemmebesøget, skal I prøve at finde en ny dato. Det er ikke et krav, at AMPS skal gennemføres for at blive inkluderet i studiet, men I skal (så vidt muligt) finde en ny dato, da det er **meget vigtigt**, at vi får AMPS-data. Dette eventuelle ekstra besøg skal lægges inden for 14 dage efter det aftalte besøg. Datoen for AMPS-testen er baseline-datoen.

**Ad. 8. Glædesskabende aktiviteter**

Du skal udfylde skemaet med de **glædesskabende aktiviteter** og spørge deltageren om følgende:

*"Nævn 2-5 aktiviteter, der giver dig glæde?"*

**Ad.9. hjælpemidler, boligændringer og observation af omgivelsesmæssige barrierer**

9.1. Listen med **hjælpemidler T1** udfyldes (vedlagt)

9.2. Listen med **boligændringer T1** udfyldes (vedlagt)

**Ad.10. Afslutning af besøget**

Du skal aftale en dato for næste opfølgning med projektdeltageren. Du skal fortælle følgende til projektdeltageren:

- Vi ringer eller sender en SMS til dig et par dage inden næste besøg for at minde dig om den aftalte dato. I det opfølgende besøg vil jeg stille de samme spørgsmål igen og observere dig i et par hverdagsopgaver i hjemmet. Inden besøget skal du også have udfyldt et spørgeskema med færre spørgsmål end det, du har udfyldt nu, og en dagbog, som vil blive sendt til dig inden besøget.

- Du må ikke fortælle mig, om du i perioden mellem dette besøg og næste opfølgende besøg har fået nogle indsatser.

- Om ca. seks uger sender vi også et nyt spørgeskema med færre spørgsmål end det, du har udfyldt nu, som du igen bedes udfylde. Men denne gang skal spørgeskemaet returneres i en vedlagt frankeret svarkuvert. I den forbindelse ringer vi også til dig for at høre, hvordan det nu er for dig at udføre de aktiviteter, som du har fortalt, du har besvær med. **Husk, at der kun bliver ringet, hvis deltageren har identificeret nogle aktivitetsproblemer i IPPA.**

- Grunden til at du skal udfylde det samme spørgeskema flere gange skyldes, at vi gerne vil vide, hvordan du klarer hverdagens aktiviteter over tid, og hvordan du generelt har det.

**Ad. 11. Efter besøget**

- Ud fra klinisk ræsonnering vurderer du og registrerer, hvilke AMPS færdigheder der henholdsvis er effektive og ineffektive. Disse og de øvrige data (papirskemaer) scanner du straks efter besøget og gemmer dem på SharePoint, hvorefter de placeres i et aflåst skab, som kun dataindsamlere og interventionsterapeuter har adgang til. Lydfiler gemmes ligeledes i SharePoint. Du registrerer, at besøget er foretaget, hvilke data der foreligger mv. i monitoreringsskemaet. Du skal ligeledes registrere tidsforbrug. Du inddaterer desuden AMPS data. Når du opretter en ny deltager i OTAP, skal du anvende ID nummer i stedet for navn og efternavn - skriv nummer ved navn og a,o eller n ved efternavn. Du skal oprette *Results Report* med angivelse af ADL-motor, ADL-process, alderssvarende ADL-motor og alderssvarende ADL-process. Du gemmer de scannede data og *AMPS Results Report* i SharePoint.
- Efter besøget registrerer dataindsamleren desuden online, at projektdeltageren skal randomiseres til enten interventions- eller kontrolgruppen på https://open.rsyd.dk/OpenRandomize. Du skal først **randomisere** deltageren, når du har **gennemført AMPS**.

**OBS: Data er personfølsomme – derfor:**

- Tag aldrig cpr-nummer med på besøget
- Hav personens navn, adresse og telefonnummer på et særskilt stykke papir adskilt fra data
- Al datamateriale mærkes med personens ID-nummer
- Pas på de indsamlede data, slip dem ikke af syne, mens de transporteres
- Data opbevares i låste skabe

# Dataindsamlingsmanual – T2 opfølgning – telefonisk opfølgning på IPPA

**Huskeliste inden opfølgningsbesøget**

Du skal bruge følgende materialer:

- De udfyldte IPPA-scoringsark fra første besøg
- IPPA-skema – interview 2 svarende til antallet af prioriterede aktiviteter ved første besøg

**Ad. 1. Introduktion**

**2.1 Formålet med dagens opfølgning**

Du skal starte med at fortælle følgende til projektdeltageren:

- Formålet med denne samtale er, at jeg skal interviewe dig om, hvordan det går med de prioriterede hverdagsopgaver, du angav ved sidste besøg. Dette gøres for at finde ud af, hvordan du klarer hverdagens aktiviteter over tid.

**Ad. 2. Spørgeskemaer**

Hvis spørgeskemaet er modtaget, skal du **tjekke at alt er udfyldt**. Mangler der svar på enkelte spørgsmål kan disse afklares og udfyldes med projektdeltageren. Hvis deltageren ikke har lyst eller kan svare på IPA-DK spørgsmål 8e, 6, kan det bare undlades. Hvis deltageren ikke har sendt spørgeskemaet retur endnu, skal du minde vedkommende om at få det gjort.

**Ad. 3. IPPA**

Du skal udføre interviewet efter retningslinjerne – se manual. Du skal sige følgende ”Jeg vil gerne høre, hvordan det nu er for dig at udføre de aktiviteter, som du tidligere fortalte, du havde besvær med”. Du skal gennemgå hver aktivitet.

**Ad.4. Afslutning af besøget**

Du skal fortælle følgende til projektdeltageren:

- Vi sender et nyt spørgeskema om ca. fem uger, som du igen bedes udfylde, men denne gang skal spørgeskemaet ikke returneres, da vi næste gang kommer hjem til dig. Inden besøget skal du have udfyldt spørgeskemaet og en dagbog, som vi også sender til dig. I det opfølgende besøg vil jeg stille de samme spørgsmål igen og observere dig i et par hverdagsopgaver i hjemmet.

- Grunden til at du skal udfylde det samme spørgeskema flere gange skyldes, at vi gerne vil vide, hvordan du klarer hverdagens aktiviteter over tid og hvordan du generelt har det.

**Ad. 5. Efter besøget**

- Hvis spørgeskemaet er modtaget, registrerer du dette i monitoreringsskemaet. Straks efter telefonsamtalen scanner du spørgeskemaet og IPPA data (papirskemaer) og gemmer dem i SharePoint, hvorefter de placeres i et aflåst skab, som kun dataindsamlere og interventionsterapeuter har adgang til. Du skal også registrere tidsforbruget.

**OBS: Data er personfølsomme – derfor:**

- Tag aldrig cpr-nummer med på besøget
- Hav personens navn, adresse og telefonnummer på et særskilt stykke papir adskilt fra data
- Al datamateriale mærkes med personens ID-nummer
- Pas på de indsamlede data, slip dem ikke af syne, mens de transporteres
- Data opbevares i låste skabe

# Dataindsamlingsmanual – T3 opfølgning

### Huskeliste inden opfølgningsbesøget

Inden besøget skal du medtage følgende materialer:

- Skemaet "Har du fået en bedre hverdag"
- De udfyldte IPPA-scoringsark fra første besøg (deltageren må ikke se disse)
- Medtag IPPA-skema – interview 2 svarende til antallet af prioriterede aktiviteter ved første besøg
- To eksemplarer af AMPS-scoringsark
- Diktafon
- Listen med registrering af hjælpemidler T3
- Listen med registrering af boligændringer T3
- Skemaet "Kemobehandling T3"
- Skemaet "Intervention eller kontrol"
- Husk frimærker og en kuvert, som kan bruges til at sende dagbogen retur, hvis deltageren har glemt at udfylde den.
- Husk AMPS-manualen

- T3 spørgeskemaet

**Manualen**

Manualen beskriver den rækkefølge de forskellige undersøgelsesredskaber skal anvendes i, samt giver forslag til indledning.

Det er vigtigt at give projektdeltageren god tid.

**Oversigt over forløbet**

12. Introduktion
13. Spørgeskemaer (EORTC-QLQ C-30, IPA-DK mv. samt dagbog)
14. Kemobehandling
15. Har du fået en bedre hverdag
16. Kvalitativt spørgsmål
17. IPPA
18. AMPS
19. Registrering af hjælpemidler og boligændringer
20. Gæt gruppe
21. Aftale næste opfølgningsdato
22. Efter besøget

**Ad. 1. Introduktion**

**3.1 Formålet med dagens besøg**

Du skal starte med at fortælle følgende til projektdeltageren:

- Formålet med dagens besøg er dels, at jeg skal interviewe dig om, hvordan det går med de prioriterede hverdagsopgaver, du angav ved sidste besøg og dels at observere dig, når du udfører et par hverdagsopgaver i dine hjemlige omgivelser. Jeg vil også høre, om din hverdag er blevet bedre siden sidste besøg. Herefter skal jeg registrere, hvilke hjælpemidler du har og om der er foretaget boligændringer i dit hjem. Hensigten med dette opfølgende besøg er at finde ud af, hvordan du klarer hverdagens aktiviteter over tid.

**Ad. 2. Spørgeskemaer og dagbog**

Du skal bede om de udsendte materialer. Hvis spørgeskemaet ikke er blevet udfyldt, skal du udfylde det sammen med deltageren. Du skal spørge, om der har været problemer med at udfylde spørgeskema og/eller dagbog. **Check at alt er udfyldt**. Mangler der svar på enkelte spørgsmål kan disse afklares og udfyldes med projektdeltageren. Hvis deltageren ikke kan svare på et spørgsmål fra IPA-dk, der er i spørgeskemaet, skal deltageren beskrive årsagen i de kvalitative spørgsmål, som afslutter hver delområde i IPA-DK. Hvis deltageren ikke har lyst eller kan svare på IPA-DK spørgsmål 8e, 6, kan det bare undlades.

**Ad.3. Kemobehandling**

3.1. Skemaet **"Kemobehandling T3"** udfyldes (vedlagt)

*OBS: Optag med diktafon: Start med at sige deltagerens ID-nr., dato, dit navn og at det er T3.*

**Ad. 4. Har du fået en bedre hverdag**

4.1 Skemaet **"Har du fået en bedre hverdag"** udfyldes (vedlagt)

**Ad. 5. Kvalitativt spørgsmål**

*Du skal spørge om følgende (Det er vigtigt, at deltageren får god tid til at svare):*

- Hvordan klarer du hverdagen og dens gøremål?

Stop optagelse med diktafon.

**Ad. 6. IPPA**

- Hvis deltageren har identificeret aktivitetsproblemer ved T1 baseline, skal du udføre interviewet efter retningslinjerne – se manual. Du skal sige følgende "Jeg vil gerne høre, hvordan det nu er for dig at udføre de aktiviteter, som du tidligere fortalte, du havde besvær med". Du skal gennemgå hver aktivitet. Når deltagerne skal score, skal de tage udgangspunkt i den dag, hvor interviewet foregår, og hvis de ikke har udført aktiviteten den dag, så ud fra den seneste gang, de udførte aktiviteten.

**Ad. 7. AMPS observation**

- Du skal udføre testen efter retningslinjerne – se manual. Med baggrund i IPPA og deltagernes dagbog skal du Indlede et AMPS-interview mhp. at identificere to relevante ADL-opgaver. Det er **vigtigt**, at de to opgaver har **en passende sværhedsgrad** (det kan være de samme opgaver som ved første besøg eller andre aktiviteter).

- Hvis du ikke kan AMPS-teste deltageren ved hjemmebesøget, skal I prøve at finde en ny dato. Dette eventuelle ekstra besøg skal lægges inden for 14 dage efter det aftalte besøg.

**Ad.8.** hjælpemidler**, boligændringer og observation af omgivelsesmæssige barrierer**

8.1. Listen med **hjælpemidler T3** udfyldes (vedlagt)
8.2. Listen med **boligændringer T3** udfyldes (vedlagt)

**Ad.9. Afslutning af besøget**

Du skal fortælle følgende til projektdeltageren:

- Vi sender et nyt spørgeskema om ca. tre måneder, som du igen bedes udfylde, men denne gang skal spørgeskemaet returneres i en vedlagt frankeret svarkuvert.

- Grunden til at du skal udfylde det samme spørgeskema flere gange skyldes, at vi gerne vil vide, hvordan du klarer hverdagens aktiviteter over tid og hvordan du generelt har det.

**Ad. 10. Efter besøget**

- Du skal udfylde skemaet **Intervention eller kontrol**

- Du registrerer, at besøget er foretaget, hvilke data der foreligger mv. i monitoreringsskemaet. Du inddaterer desuden tidsforbrug og AMPS data. Når du opretter en ny deltager i OTAP, skal du anvende ID nummer i stedet for navn og efternavn - skriv nummer ved navn og a,o eller n ved efternavn. Du skal oprette *Results Report* med angivelse af ADL-motor, ADL-process, alderssvarende ADL-motor og alderssvarende ADL-process. Straks efter besøget scanner du data (papirskemaer) og gemmer dem i SharePoint, hvorefter de placeres i et aflåst skab, som kun dataindsamlere og interventionsterapeuter har adgang til. Lydfiler gemmes ligeledes i SharePoint. Du gemmer de scannede data og *AMPS Results Report* i SharePoint.

**OBS: Data er personfølsomme – derfor:**

- Tag aldrig cpr-nummer med på besøget
- Hav personens navn, adresse og telefonnummer på et særskilt stykke papir adskilt fra data
- Al datamateriale mærkes med personens ID-nummer
- Pas på de indsamlede data, slip dem ikke af syne, mens de transporteres
- Data opbeva

# Paper I

Brandt et al. BMC Palliative Care (2016) 15:10
DOI 10.1186/s12904-016-0084-9

BMC Palliative Care

STUDY PROTOCOL Open Access

# Effectiveness of the "Cancer Home-Life Intervention" on everyday activities and quality of life in people with advanced cancer living at home: a randomised controlled trial and an economic evaluation

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## Abstract

**Background:** During the past decade an increasing number of people live with advanced cancer mainly due to improved medical treatment. Research has shown that many people with advanced cancer have problems with everyday activities, which have negative impact on their quality of life, and that they spend a considerable part of their time at home. Still, research on interventions to support the performance of and participation in everyday activities is only scarcely available. Therefore, the occupational therapy-based "Cancer Home-Life Intervention" consisting of tailored adaptive interventions applied in the participant's home environment was developed. The objective of this study is to examine the effectiveness and cost-effectiveness of the Cancer Home-Life Intervention compared to usual care on the performance of and participation in everyday activities and quality of life in people with advanced cancer living at home.

**Methods:** The study is a randomised, controlled trial (RCT) including an economic evaluation. The required sample size of 272 adults living at home will be recruited from outpatient clinics at two Danish hospitals. They should be diagnosed with cancer; evaluated incurable by the responsible oncologist; and with a functional level 1–2 on the WHO performance scale. The primary outcome is the quality of performance of activities of daily living. Secondary outcomes are problems with prioritised everyday activities; autonomy and participation; and health-related quality of life. Participants are randomly assigned to: a) The Cancer Home-Life Intervention in addition to usual care, and b) Usual care alone.

**Discussion:** The trial will show whether the Cancer Home-Life Intervention provides better support for people with advanced cancer living at home in performing and participating in everyday activities, and whether it contributes to their health-related quality of life. The economic evaluation alongside the RCT will show if the Cancer Home-Life Intervention is cost-effective. The trial will also show the acceptability of the intervention to the target group, and whether subgroups of participants will benefit more than others.

**Trial registration:** ClinicalTrials.gov Identifier NCT02356627. Registered 02/02/2015.

**Keywords:** Palliative care, Supportive care, Health-related quality of life, Activities of daily living, Home based intervention, Occupational therapy, Economic evaluation, Randomized controlled trial

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## Background

The number of people living with advanced cancer is increasing [1], and it is estimated that the majority of these people are in need of palliative care [2, 3]. According to the World Health Organization (WHO), some of the goals of palliative care are to alleviate adverse consequences of the disease, to improve the quality of life, and to help patients with life-threatening illness to live as actively as possible [4]. Advanced cancer, defined as cancer diagnosed as incurable by the responsible oncologist, can cause functional limitations [5, 6], which may result in decreased ability and energy to perform everyday activities, such as self-care, household, leisure and work [7–9]. A recent study found that 48 % of patients with advanced cancer ($N = 977$) had problems with everyday activities, and that 29 % had unmet needs regarding these [2]. In another study, more than 43 % of women with metastatic breast cancer ($N = 163$) had difficulties with activities of daily living (ADL) and 74 % with instrumental activities of daily living (IADL) [10]. Further, in a study of people with advanced cancer, 10-30 % reported that they had needs in performing everyday activities, i.e. activities that, in addition to ADL and IADL, include leisure and work [11]. Consequently, many people with advanced cancer are not able to perform needed and desired everyday activities, which may lead to reduced quality of life for the individual [12, 13].

Despite the knowledge about the problems and needs of people with advanced cancer related to everyday activities, palliative care rarely encompasses interventions that focus on enabling everyday activities [14–16], and little is known about how the everyday activities are specifically affected and what kind of support is needed. Prior to the present study, a cross-sectional study was conducted to delineate the everyday activity problems, particularly in regard to ADL performance, activities prioritised to be solved, and intervention needs [17–19]. In all, 164 participants with an advanced cancer, a mean age of 67 years, and a WHO Performance Status of 1–3 were included. The findings showed that many participants had functional limitations such as fatigue and pain, and that their ADL performance was characterised by increased effort and reduced efficiency, safety and independency. About half had ADL motor ability below age expectations. The ADLs that caused most problems were physically demanding activities such as cleaning, laundering, and cooking, while fewer problems with self-care were found [18]. The study showed that the everyday activities which the participants had problems with and prioritised being solved mostly concerned leisure, social and domestic activities, along with a wish for improved mobility, autonomy and participation [18].

A Danish randomised controlled trial (RCT) demonstrated that an activity-focused hospital-based intervention was feasible for people with advanced cancer [20]. The study did not identify superior effect of the intervention partly due to a small sample size [21]. A systematic review has indicated that home-based interventions can improve health-related quality of life and satisfaction with palliative care, reduce depressive symptoms, societal costs, and the number of hospital admissions [22]. In addition, a study has shown that people with advanced cancer spend a considerable part of their time at home [23]. Hence a home-based intervention may be more appropriate than a hospital-based intervention in order to enable everyday activities for people with advanced cancer.

We only identified one home-based intervention study aimed at supporting everyday activities for people with cancer. Hegel et al. performed a pilot RCT of a telephone-delivered problem-solving occupational therapy intervention lasting less than a mean time of 106 min. They found that participation restrictions in everyday activities among rural breast cancer patients undergoing chemotherapy seemed to be decreased due to the intervention [24]. When searching for interventions for groups with activity problems similar to those of people with advanced cancer, such as people with chronic diseases and older people with functional limitations, we only identified few studies. The interventions mainly consisted of adaptation of everyday activities, energy conservation, provision of assistive or mainstream technologies, and home modifications, resulting in improved functioning in everyday activities and quality of life [25–29].

Based on the cross-sectional study, existing studies and available guidelines, a literature review, and consultation with representatives of the target group, the "Cancer Home-Life Intervention" was developed and pilot-tested. The intervention applies adaptive strategies, defined as individual plans to overcome particular challenges or to meet the needs of the study participants [30, 31], and aims to compensate for functional limitations, enhance participation in everyday activities, and support resource/energy preserving activity patterns of people with advanced cancer. The intervention has undergone a small feasibility trial ($N = 4$) showing that the intervention was acceptable for the study participants and possible to implement. Since the Cancer Home-Life Intervention is newly developed an evaluation of its effectiveness and cost-effectiveness is required prior to wider implementation. This study protocol outlines how we intend to conduct such evaluation.

## Study objective

The overall objective of this study is to examine the effectiveness and cost-effectiveness of the Cancer Home-Life Intervention compared to usual care on the performance

of and participation in everyday activities and health-related quality of life in people with advanced cancer living at home.

#### Specific aims

- To examine the effectiveness of the Cancer Home-Life Intervention in terms of quality of ADL performance as a primary aim and in terms of problems with everyday activities prioritised to be solved; autonomy and participation in the dwelling; and health-related quality of life as secondary aims.
- To investigate whether the Cancer Home-Life Intervention is especially effective in some subgroups of people with advanced cancer defined by age, gender, primary cancer diagnosis, and the WHO Performance score.
- To explore how people with advanced cancer experience the usefulness of the intervention, and how activity patterns change over time in the two groups.
- To investigate the cost-effectiveness of the Cancer Home-Life Intervention.

#### *Hypotheses*

- The quality of ADL performance as demonstrated by motor and process ability will be better in participants undergoing the Cancer Home-Life Intervention compared to participants who receive usual care.
- Participants undergoing the Cancer Home-Life Intervention will report less difficulty with prioritised everyday activities, better autonomy and participation, and higher levels of health-related quality of life compared to participants who receive usual care.
- The Cancer Home-Life intervention provides more Quality Adjusted Life Years (QALYs) at a higher incremental cost.
- The Cancer Home-Life intervention is cost-effective in a health sector perspective.

## Methods

### Trial design

The study is designed as a RCT using a combination of quantitative and qualitative methods. A health economic evaluation will be performed alongside the RCT.

### Participants

Study participants will be enrolled consecutively from Aarhus University Hospital (OUH) and Odense University Hospital (AUH) in Denmark. Participants who fulfil the following inclusion criteria will be enrolled in the study:

*Inclusion criteria:*

- ≥18 years old
- Diagnosed with cancer
- Evaluated incurable by responsible oncologist in respective out-patient clinic
- Functional level 1–2 on the WHO performance scale as assessed by hospital nurses or the project occupational therapist (P-OT) [32]
- Live within a radius of maximum 60 km from AUH or on the island of Funen
- Live in a private home or in sheltered living
- Know sufficient Danish to complete questionnaires and participate in interviews

*Exclusion criteria:*

- Cognitive impairment preventing the participant to complete the structured interview as assessed by a P-OT during the interview prior to enrolment
- Live in a nursing home or a hospice
- Considered incapable of complying with the trial by a P-OT

### Enrolment procedure

At each participating hospital, nurses, secretaries, or the Palliative Team will screen all potential participants for inclusion in the study during 24 months. When eligible participants are identified, the contact information is given to a P-OT responsible for enrolment of study participants. The P-OT will contact all potential participants and provide detailed verbal and written information about the study. Prior to inclusion, the study participants are to give written permission.

## Intervention and control

### Intervention

The Cancer Home-Life Intervention is described in a detailed intervention manual (unpublished, can be retrieved from the authors) and is provided by trained Intervention Occupational Therapists (I-OT). The intervention program is occupational therapy-based and encompasses individually tailored combinations of the following elements: 1) prioritisation of resources, energy, and everyday activities; 2) adaptation of activities; 3) adaptation of posture and seating positioning; 4) provision of assistive devices; 5) modification of the physical home environment. Intervention elements are selected in co-operation between the participant and the I-OT by means of an interview with the participant based on the individual's problems and needs. The intervention is provided through instruction in and training of the selected strategies, such as how to conduct activities in energy conserving and strain minimizing ways, and guidance and

training in safe and efficient use of assistive devices. It is provided in the participant's home within a week after baseline data collection and completed within three weeks after the initial home visit. The intervention will encompass 1–3 home visits followed by 1–3 telephone calls. When needed, the participant can also contact the I-OT.

In addition to the Cancer Home-Life Intervention, the participants in the intervention group will receive usual care as offered by the hospital and municipality. Usual care aimed at enhancing everyday activities of people with advanced cancer sometimes consists of provision of assistive devices and home modifications, but not necessarily provided systematically. All participants will be allowed to use available medical services such as rehabilitation and palliative care.

Four I-OTs, two at each hospital, will provide the intervention after having attended a one-day training course in the application of the Cancer Home-Life Intervention. Regular meetings will be held with the I-OTs in order to ensure that the intervention is applied according to the manual and as similar as possible across hospitals. The I-OTs will document adherence to the intervention manual by registering which components of the Cancer Home-Life Intervention they have provided to each participant. The study participants will register in a structured questionnaire which everyday activity enabling interventions they have been offered and report whether they have used them.

### Control

Participants in the control group will receive usual care as offered by the hospital and municipality, described above.

## Instrumentation

### Primary outcome

Quality of ADL performance is measured by *The Assessment of Motor and Process Skills (AMPS)* [33]. The AMPS is a standardised, observation-based assessment designed to evaluate the quality of a person's ADL performance regarding ease, efficiency, safety, and independence. A trained and calibrated P-OT observes the quality of 16 motor and 20 process performance skills (ADL ability) while the person performs two familiar and relevant ADLs, and rates the person's performance of each skill on a four-point ordinal scale. The ADL motor ability is a measure of how much physical effort, clumsiness, and/or fatigue the person demonstrates during ADL performance. The ADL process ability is the person's overall efficiency regarding appropriate use of time, space, and objects throughout ADL performance. The ordinal scores are converted into two overall linear ability measures by Rasch-based computer-scoring software: one for ADL motor ability and one for ADL process ability expressed in logistically transformed probability units (logits). The two overall linear ability measures are adjusted for task challenge, skill item difficulty, and rater severity. ADL motor ability above 2.0 logits and ADL process ability above 1.0 logits indicate competent ADL performance, and 0.3 logits a clinical relevant change [33]. In the present study, the ADL motor ability is used as the primary outcome. The P-OT also assesses the five most effective and the five most ineffective ADL motor and process skills based on clinical reasoning [33]. The AMPS has been found valid and reliable in people with advanced cancer [34, 35] and responsive in people with other disorders [33].

### Secondary outcomes

#### *Problems with everyday activities prioritised to be solved*

Problems with everyday activities at home that the participants face and prioritise to have solved, will be assessed using the *Individually Prioritised Problems Assessment (IPPA)* [36]. The instrument has a structured interview format where the participant identifies up to seven everyday activity problems and rates the importance of and ease/difficulty with each of these problems on five-point ordinal scales from 1 to 5, where 1 = not important at all and 5 = most important; and 1 = no difficulty at all and 5 = too much difficulty to perform the activity at all. The importance scores and the difficulty scores of each activity are multiplied. The scores are then added up and divided by the number of activity problems, resulting in an average IPPA score between 1 and 25. Higher average IPPA scores indicate more difficulty with the prioritised everyday activities [36]. The IPPA has been found to be a useful, responsive, and valid instrument in older people who use assistive devices [37, 38].

#### *Autonomy and participation in the dwelling*

Autonomy and participation are assessed using three subscales of the Danish version (IPA-DK) of the *Impact on Participation and Autonomy Questionnaire (IPAQ)* [39, 40]. The IPA-DK is a questionnaire targeting adults with chronic functional limitations. It assesses person-perceived participation restrictions via 32 items organised into five subscales: 1. Autonomy indoors, 2. Family roles, 3. Autonomy outdoors, 4. Social life and relationships, and 5. Work and education. For this study, the subscales 1, 2, and 4 are used. Response options are given on five-point ordinal scales from 0 = very good to 4 = very poor. In addition, there are nine items which quantify the degree to which the respondents perceive these restrictions as problematic in their daily life. As these are used for clinical decision making, they are not included in this study. IPAQ is available in several language versions which have well-documented psychometric properties,

and the Danish version has undergone a reliability test with satisfactory results [39].

#### *Health-related quality of life*

Health-related quality of life will be assessed by means of *The European Organization for Research Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ C-30)* [41], designed to assess the health-related quality of life of persons with cancer. The instrument consists of nine scales assessing: physical function, role function, emotional function, cognitive function, social functioning, global health status/quality of life, fatigue, nausea and vomiting, and pain, and six single-item scales: dyspnoea, insomnia, lack of appetite, constipation, diarrhoea, and financial difficulties. All the scales and single-item measures range in a score from 0 to 100. Higher score represents a higher ("better") level of functioning or a higher ("worse") level of symptoms [41]. The EORTC QLQ C-30 is a well-validated and reliable instrument within cancer research [42, 43]. Additionally, health-related quality of life will be measured by the use of the *EuroQol instrument (EQ-5D-5L)* [44]. The EQ-5D-5L is a generic instrument measuring health-related quality of life, and it is widely used in economic evaluations. The instrument consists of five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The participant scores each dimension on a five-point ordinal scale ranging from no problems to severe/extreme problems. A Danish set of preference values was constructed based on interviews with 1332 Danish respondents [45]. The psychometric properties of the EQ-5D-5L including the Danish version have been extensively investigated and are considered as good [46]. The data from the EQ-5D-5L will be used for the economic evaluation alongside the RCT.

### Descriptive data

#### *Everyday activity pattern*

The everyday activities that the participants engage in during a day will be captured by the Time Geographical method using a semi-structured diary [47]. The participants will be required to record the activities they undertake during one day of their own choice. The diary encompasses domains regarding which activities the participants engage in during the day, at what time, for how long, whom they are with, where they are, and how they feel physically and mentally [47].

#### *Joyful activities*

As a way to better understand what activities are of importance to the participants they are asked which everyday activities they regard as especially joyful [48].

#### *Experienced usefulness*

Participant observations will be conducted during 10–20 intervention sessions depending on the number of interventions provided for the individual participants [49]. In addition, telephone interventions provided to this sub-sample will be electronically recorded. In particular, attention will be on the participants' reactions to the intervention as it takes place.

Qualitative interviews will be conducted in conjunction with data collection at follow-up in the participants' homes. The interviews that will explore the usefulness of the intervention will be based on an interview guide developed from a preliminary analysis of the previous participant observations to acquire the participants' experiences of the intervention received and its usefulness.

### Cost data

#### *Intervention costs*

The intervention costs will be measured based on micro costing including occupational therapists' and study participants' time spent on the intervention; the costs for applications and assistive devices and home modifications; the occupational therapists' time used for related administrative purposes and transportation.

#### *Costs in the secondary health care sector*

The costs of secondary health care will be determined by Diagnostic Related Group (DRG) tariffs extracted from the National Patient Registry (NPR). The data include information on hospital departments, dates of admission and discharge, and diagnosis [50].

#### *Costs in the primary health care sector*

Data on the use of primary health care including contacts to general practitioners, medical specialists, and physiotherapists will be extracted from The Danish National Health Service Register for Primary Care (NHSR) and valued using the activity-based fees that are used to reimburse these providers. The NHSR contains information about the activities of health professionals' contacts with the tax-funded public health care system [50].

#### *Prescriptive medication*

Data on the use of prescriptive medication will be extracted from the Danish National Register of Prescriptive Medication. This database includes information on all redeemed prescriptive medication and the associated costs.

#### *Study participants' out-of-pocket costs*

Out-of-pocket costs such as non-prescriptive medication, dietary supplements, informal care, aids, and short term sick leave are assessed using a modified version of

the Dutch cost diary [51]. The patient out-of-pocket costs will solely be included in the sensitivity analysis.

#### *Productivity costs*

This will be calculated using data on the number of weeks of sick leave obtained from the Danish Register for Evaluation of Marginalization (DREAM), which is administered by the Danish Ministry of Employment. This database includes information on all public transfer payments for all Danish citizens registered on a weekly basis since 1991 [52]. The productivity costs per study participant will be calculated using the Human Capital method [53]. Productivity costs will solely be included in the sensitivity analysis.

## Sample size

Two hundred and seventy two participants will be enrolled. The sample size calculation was based on the mean ADL motor ability as identified in the cross-sectional study to be 1.04 logits with a standard deviation (SD) of 0.727 logits [18]. For a two-sample *t*-test of normal distribution with a two-sided significance level of 0.05 and a common SD of 0.727, a sample size of 184 participants (92 per group) would provide 80 % power to detect a between-group difference of 0.3 logits [33]. To achieve this number, the study needs a total of 272 participants (136 per group), expecting a dropout rate based on previous studies of 32 % at 12 weeks follow-up [14, 16, 24, 54].

A sub-sample of ten participants will be recruited among the entire sample using purposive sampling for participant observations during intervention sessions and for qualitative interviews [48]. Specific criteria for selection will be defined prior to actual sampling.

## Data collection

Data will be collected at baseline (T1) by means of a study specific questionnaire (demography, health, cost diary, the IPA-DK, EORTC QLQ C-30, and the EQ-5D-5 L) and the One Day Diary. The questionnaire and the One Day Diary are sent out before a home visit by the P-OTs, where the AMPS and IPPA are applied, and a question about joyful activities and one about how they manage their everyday life are asked. In addition, data concerning use of assistive devices using a study specific questionnaire are collected. The two ADLs that the participant will perform for the AMPS observation are selected on basis of the One Day Diary and the IPPA data. See Fig. 1 and Table 1. The quality of AMPS data will be monitored by Center for Innovative OT Solutions, USA, and only valid data will be included.

There will be three follow-up occasions where cost data from registers are also extracted, while demographic data are only collected at T1:

T2) Six weeks after T1: a postal questionnaire identical to the one sent out at T1 and a study specific questionnaire on the type of interventions both groups have received and/or completed. Besides, an IPPA telephone interview is accomplished.

T3) 12 weeks after T1: identical to T1 except that a question whether their everyday life has improved is also asked.

T4) 24 weeks after baseline: a postal questionnaire that includes the cost diary and the EQ-5D-5L.

Observation based data are collected in conjunction with the intervention, and qualitative interviews with a subsample are accomplished at T3.

## Randomisation

Study participants will be randomly assigned to either the intervention group (receiving the Cancer Home-Life Intervention as a supplement to usual care) or the control group (receiving usual care and not receiving the Cancer Home-Life Intervention). See Fig. 1.

Randomisation will be carried out after T1 by an administration office, which is independent of the trial. Participants will be randomly assigned in a preset block size to either the intervention or control group with a 1:1 allocation by a computer-generated randomisation schedule. The block size will be kept unknown to all investigators and P-OTs and will not be revealed until the study has ended. The randomisation is stratified by centre.

## Blinding

Allocation is concealed to the study investigators. The P-OTs will also be sought blinded for the group allocation even though they may discover this when collecting follow-up data, and the study participants are told not to reveal their group allocation to the P-OTs during the follow-up occasions. At T3 the P-OTs will be asked to guess the group allocation of the participants. This may indicate if the blinding has succeeded. Allocation status cannot be blinded for the participants.

## Analysis

### Data analyses of the clinical evaluation

Scores will be calculated following the instructions in each instrument manual and presented by descriptive statistics. The intervention group will be compared with the control group by means of a multiple linear regression analysis in continuous data (AMPS, EORTC QLQ C-30 and IPPA), given the assumptions are fulfilled. If the assumptions are not met, a relevant transformation or logistic regression will be used. IPA-DK data are ordinal and will be dichotomised before logistic regression analysis is applied. The analysis of all outcomes will

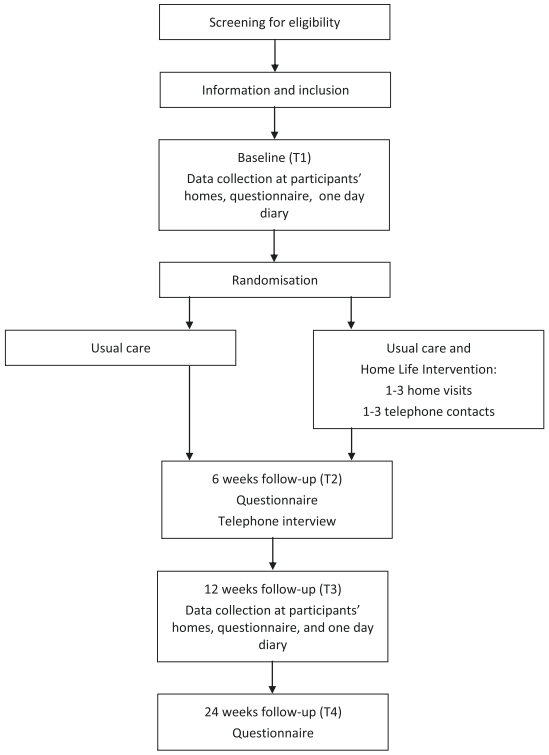


**Fig. 1** Randomisation and data collection

be adjusted for the stratification variable, centre. If there is significant imbalance between the two groups we shall consider adjusting for baseline ADL motor ability, baseline ADL process ability, gender, age, primary cancer diagnosis, education, employment and the EORTC QLQ-C30 global health status/quality of life in a sensitivity analysis [55, 56]. The between-group differences in continuous and dichotomised data will be presented with 95 % confidence intervals. A complete case analysis excluding participants without post-randomisation data will be performed [57]. It will be supplemented with a sensitivity analysis applying multiple imputation used to estimate a plausible value for the missing data of study participants lost to follow-up of other reasons than death [58].

Analyses will be performed to identify groups in which the Cancer Home-Life Intervention is especially effective. A subgroup-treatment effect interaction by a multiple regression analysis will be performed with the following possible variables as effect modifiers: age, gender, primary cancer diagnosis and WHO Performance score [59, 60].

*P* values ≤0.05 will be considered statistically significant. Analyses will be performed using STATA.

The One Day Diary data from T1 and T3 will be coded thematically into the following structure: 1) The activity domain comprising seven categories: self-care; care for others; household; leisure; transportation; procurement and preparation of food; and work. 2) The geographical domain: location and movements. 3) The social context: social circle and interaction. 4) The experiential domain: physical state and state of mind. The analyses will be used to describe the study participants' daily activities with regard to each domain including duration and frequency of activities as well as activity patterns for the individual over the time of a day [47].

Field notes from the participant observations will be transcribed into a coherent text. Interviews will be

**Table 1** Schedule for collection of outcomes and cost data

| Outcome | Source | Data collection method | Baseline T1 | Week 6 T2 | Week 12 T3 | Week 24 T4 |
|---|---|---|---|---|---|---|
| Everyday activities | | | | | | |
| Quality of ADL performance | AMPS | Observation | X | | X | |
| Problems with everyday activities | IPPA | Structured interview | X | X | X | |
| Autonomy and participation | IPA-DK | Questionnaire | X | X | X | |
| Health-related Quality of Life | | | | | | |
| Health-related quality of life | EORTC QLQ C-30 | Questionnaire | X | X | X | |
| Economic evaluation | | | | | | |
| Quality Adjusted Life Years (QALY) | EQ-5D-5L | Questionnaire | X | X | X | X |
| Intervention costs | | Questionnaire | | X | | |
| Costs in the secondary health care sector | The National Patient Registry | Register | X | X | X | X |
| Costs in the primary healthcare sector | The Danish National Health Service Register for Primary Care | Register | X | X | X | X |
| Prescriptive medication | Danish Register of Prescriptive Medication | Register | X | X | X | X |
| Out-of-pocket costs | | Cost diary | X | X | X | X |
| Productivity costs | The Danish Register for Evaluation of Marginalization | Register and questionnaire | X | X | X | X |

*AMPS* The Assessment of Motor and Process Skills, *EORTC QLQ-C30* The European Organization for Research Treatment of Cancer Quality of Life Questionnaire Core 30, *EQ-5D-5L* The EuroQol 5-dimensions 5 levels, *IPA-DK* The Danish version of the Impact on Participation and Autonomy Questionnaire (IPAQ), *PPA*, The Individually Prioritised Problems Assessment

transcribed verbatim. Both data sets will be analysed by thematic analysis to unfold and understand how the participants reacted to and experienced the usefulness of the received interventions, and to explore how the intervention worked and what aspects had particular relevance for the participants [48]. Thereafter, data derived from participant observations and interviews will be analysed with a constant comparative method. The analysis involves comparing different types of data from the two methods in order to systematically trace out categories and relationships within the data [61].

### Data analysis for the economic evaluation

The economic evaluation will be conducted as a cost-effectiveness analysis. A health sector viewpoint will be taken to estimate the costs of all activities and resource use related to the study participants' disease. T1 will be taken as the start of the time frame that will end at T4. All costs will be reported in 2015-Euros. By the use of register data to estimate costs, we expect a full follow-up of these data. The method of multiple imputation [58] will be used to handle possible lost to follow-up in the ADL motor ability or the EQ-5D-5L due to other reasons than death.

In the cost-effectiveness analysis the ADL motor ability will be used as the clinical parameter and QALY will be used as the measure of utility. In order to calculate QALY the EQ-5D-5L the recommended standard mapping procedure will be used based on the Danish preference weights [45]. The QALYs over 24 weeks will be calculated by interpolation of the area under the curve with four time points (T1, T2, T3, and T4). The resource use, costs, and clinical outcome will be presented as means with 95 % bootstrapped confidence intervals (10,000 replicates) [62]. The Incremental Cost-Effectiveness Ratio (ICER) will be calculated using the formula: $ICER = (C_A - C_B) / (E_A - E_B)$, where C denotes costs and E denotes effects with A and B referring to comparators. The ICER summarises the results of each economic evaluation in a single parameter, defined as the ratio of additional costs per additional unit of effect [53]. The ICER is, however, undefined if the ratio or just one of the confidence limits is negative.

The result of the cost-effectiveness analysis will be summarised in cost-effectiveness acceptability curves (CEAC) [63]. A CEAC is a graphic representation of the uncertainty in cost differences and effect differences between the two groups [63]. To deal with the structural uncertainties, sensitivity analysis will be performed to test the influence of the chosen imputation strategy. Further sensitivity analysis will be performed to test the inclusion of productivity costs and patients' out-of-pocket payments [53].

## Ethical considerations

All participants enrolled in the project will receive written and oral information about the project procedures and will have volunteered to participate, which will be verified by written consent. All eligible participants will be informed that they are free to withdraw from the

study at any time without consequences for their future care. The trial will be conducted in accordance with the ethical principles outlined in the Declaration of Helsinki 2008 [64]. According to the Danish Regional Scientific Ethical Committee regulations the project is not notifiable, because no human biological material is included in the project (S-20122000-96). Permission to obtain and store data was originally given by the Danish Data Protection Agency (J.nr. 2012-41-1404), but controllership has later (March 27 2015) been transferred to the umbrella/joint notification of Southern Denmark to the Danish Data Protection Agency of University (FN 215-57-0008). The intervention group will be treated by authorised occupational therapists trained specifically for the present study. Since the control group will be offered the care that is usually given, and the outcome of the Cancer Home-Life Intervention is expected to have a positive impact on the everyday activities of people with advanced cancer, allocation to either the control group or the intervention group is ethically acceptable. No adverse effects of the planned intervention are expected. However, because the participants suffer from a life-threatening disease, the assessments may cause emotional reactions [65]. This will be handled in an ethically appropriate manner: all participants will receive a telephone number so that they can contact the research team if needed, and time is allocated for the P-OTs and the I-OTs to talk to the participants if required. All results will be handled confidentially, and only group results will be published.

The project is approved by the Danish Data Protection Agency (J.nr. 2012-41-1404). Data will be stored in locked filing cabinets or in password-protected computers at the University of Southern Denmark, archived in accordance with University guidelines and the Danish Data Protection Agency.

The study is registered in www.controlled-trials.com/ClinicalTrials.gov (NCT02356627).

## Discussion

The present study will contribute with knowledge about whether the Cancer Home-Life Intervention can support people with advanced cancer living at home in performing and participating in prioritised everyday activities, and whether the intervention contributes to their health-related quality of life. So far knowledge about improving and preserving everyday activities of people with advanced cancer is scarce. Given that these people live longer and are increasingly receiving medical treatment on an outpatient basis, they need to be able to manage or live an everyday life according to their own wishes; there is a definite need for such knowledge.

A strength of the study is that parts of it are based on the previous cross-sectional study serving as a kind of feasibility study as recommended by The Medical Research Council [66]. For instance we gained experience with ways of recruiting from hospitals, time use and procedures for data collection; we got knowledge about the demographics and clinical characteristics of the study population and which everyday activities they had problems with, and which they would like to have solved. Most importantly the cross-sectional study provided empirical information that could be used to calculate the sample size on basis of our primary outcome measure. The calculation was therefore based on the required number of participants at T3, taking expected drop-out into account in order to get sufficient power to detect possible effects. Another strength is that we involved a patient expert group consisting of representatives of people with advanced cancer to advise us about the contents and feasibility of the Home-Life Intervention and piloted the procedures and the intervention prior to trial start ($N = 4$).

One of the challenges encountered in the cross-sectional study was the mortality of the study population. For instance only ten of the 84 study participants included from OUH were alive one and a half year after completion of the cross-sectional study. The consequence may be that a substantial part of the study participants may not be alive at the 24 weeks' follow-up (T4). Since data from T4 are solely used for the economic evaluation and mostly consist of register based data, it still is possible to get useful results.

The study is one of the first to investigate the effect of everyday activity interventions for people with advanced cancer in the home. In addition to data on the effectiveness of the Cancer Home-Life Intervention, the study will provide information about the cost-effectiveness of the intervention, its acceptability for the target group, and whether some subgroups might benefit more than others from the intervention. Hence the study will yield comprehensive knowledge that can be applied in palliative care in case of positive results; if so, the next step will be to investigate how to implement the Cancer Home-Life Intervention in municipality palliative care.

#### Abbreviations

ADL: Activities of daily living; AMPS: The Assessment of Motor and Process Skills; AUH: Aarhus University Hospital; CEAC: Cost-effectiveness acceptability curve; DREAM: The Danish Register for Evaluation of Marginalization; DRG: Diagnosis related group; EORTC QLQ-C30: The European Organization for Research Treatment of Cancer Quality of Life Questionnaire Core 30; EQ-5D-5 L: The EuroQol 5-dimensions 5 levels; ICER: Incremental Cost-Effectiveness Ratio; I-OT: Intervention Occupational Therapist; IPA-DK: The Danish version of the Impact on Participation and Autonomy Questionnaire (IPAQ); IPPA: The Individually Prioritised Problems Assessment; NPR: The National Patient Registry; NHSR: The Danish National Health Service Register for Primary Care; OUH: Odense University Hospital; P-OT: Project occupational therapist; QALY: Quality Adjusted Life Years; RCT: Randomised controlled trial; WHO: World Health Organization.

#### Competing interests

The authors declare that they have no competing interests.

**Authors' contributions**
ÅB and KIC conceived the original idea for the trial, sought and obtained funding. KIC is the grant recipient. ÅB, KIC, MSP, LGOE, LL-J, ATJ and JS contributed to the design of the trial. LL-J and KIC developed the intervention. ÅB is the daily project leader, and MSP and ÅB are project co-ordinators. MSP will undertake all quantitative data analyses, KIC the qualitative data analyses, and LGOE the economic evaluation. ÅB, KIC, MSP and LGOE wrote the manuscript with input from the other authors. ÅB and KIC are guarantors for this paper. All authors read and approved the final manuscript.

**Acknowledgements**
We are grateful for the advice from the members of the project Advisory Board on the study design: Professor Malcolm Cutchin, Wayne State University, USA; Professor Anders Bonde Jensen, Aarhus University Hospital; Professor Jens Søndergaard, University of Southern Denmark. We also wish to thank Statistician, PhD, René dePont Christensen, University of Southern Denmark, for giving statistical advice, and participants in the patient expert group from Funen for giving advice about the intervention. The trial is funded by The TrygFonden and The Danish Cancer Society (7 mill. DKK).

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Received: 12 October 2015 Accepted: 19 January 2016

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# Paper II

*Original Article*

PALLIATIVE MEDICINE

*Palliative Medicine*
1–13

DOI: 10.1177/0269216317747199
journals.sagepub.com/home/pmj
SAGE

# The 'Cancer Home-Life Intervention': A randomised controlled trial evaluating the efficacy of an occupational therapy–based intervention in people with advanced cancer

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## Abstract

**Background:** People with advanced cancer face difficulties with their everyday activities at home that may reduce their health-related quality of life. To address these difficulties, we developed the 'Cancer Home-Life Intervention'.

**Aim:** To evaluate the efficacy of the 'Cancer Home Life-Intervention' compared with usual care with regard to patients' performance of, and participation in, everyday activities, and their health-related quality of life.

**Design and intervention:** A randomised controlled trial (ClinicalTrials.gov NCT02356627). The 'Cancer Home-Life Intervention' is a brief, tailored, occupational therapy–based and adaptive programme for people with advanced cancer targeting the performance of their prioritised everyday activities.

**Setting/participants:** Home-living adults diagnosed with advanced cancer experiencing functional limitations were recruited from two Danish hospitals. They were assessed at baseline, and at 6 and 12 weeks of follow-up. The primary outcome was activities of daily living motor ability. Secondary outcomes were activities of daily living process ability, difficulty performing prioritised everyday activities, participation restrictions and health-related quality of life.

**Results:** A total of 242 participants were randomised either to the intervention group ($n=121$) or the control group ($n=121$). No effect was found on the primary outcome (between-group mean change: –0.04 logits (95% confidence interval: –0.23 to 0.15); $p=0.69$). Nor was any effect on the secondary outcomes observed.

**Conclusion:** In most cases, the 'Cancer Home-Life Intervention' was delivered through only one home visit and one follow-up telephone contact, which not was effective in maintaining or improving participants' everyday activities and health-related quality of life. Future research should pay even more attention to intervention development and feasibility testing.

## Keywords

Activities of daily living, independent living, neoplasms, occupational therapy, quality of life, palliative care, controlled clinical trial

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**What is already known about the topic?**

- Many people with advanced cancer want to stay at home for as long as possible.
- Research shows that people with advanced cancer have difficulties performing and participating in everyday activities at home, and this may reduce their health-related quality of life (HRQoL).
- Only two pilot studies and an underpowered randomised controlled trial (RCT) have so far investigated the efficacy of occupational therapy–based (OT-based) interventions that support people with advanced cancer in performing and participating in everyday activities.

**What this paper adds?**

- It was feasible to conduct a full-scale RCT for people with advanced cancer.
- The majority of the participants wanted and needed OT-based interventions that supported their everyday activities at home.
- We found no effect of the 'Cancer Home-Life Intervention' on activities of daily living (ADL) performance, difficulty performing prioritised everyday activities, autonomy and participation, or HRQoL.

**Implications for practice, theory or policy**

- This is the first full-scale, sufficiently powered RCT to investigate the efficacy of an OT-based intervention in people with advanced cancer.
- Future RCTs evaluating efficacy of OT-based interventions in this population require even more attention to intervention development and feasibility testing.
- Future studies need to consider if patients selected for their studies should have more severe functional limitations than was the case in our study and if the intervention is relevant to patients.

## Introduction

More people live longer with advanced cancer,[1,2] and many of them want to stay at home for as long as possible.[3,4] Research shows that most people with advanced cancer have difficulties performing and participating in everyday activities,[5–10] which can affect their ability to stay at home and in turn reduce their health-related quality of life (HRQoL).[11] Everyday activities refer to everything people do in daily life, like self-care and housework (activities of daily living (ADL)), work and leisure,[12] with ADL being essential for maintaining independent living.[13]

Several qualitative studies emphasise that maintaining everyday activities and independence is an important priority for people with advanced cancer.[14–18] However, Cheville et al.[5] showed that more than 43% of women with metastatic breast cancer ($N=163$) had difficulties performing ADL. Rainbird et al.[10] revealed that 10%–30% of people with advanced cancer ($N=246$) needed help with housework and preparing meals, 31% feared losing their independence and 40% were frustrated by being unable to participate in the activities they used to do previously. This resonates with a study by Johnsen et al.[6] where 29% ($N=901$) of people with advanced cancer did not receive the help they need concerning ADL. Similarly, Wæhrens et al.[8] found that among people with advanced cancer, 53% ($N=136$) had an observed ADL performance level requiring assistance to perform ADL and prioritised everyday activity problems mainly within mobility and domestic life.[9] Thus, to support people with advanced cancer in living their lives as fully as possible, palliative care must also focus on enabling the patients' everyday activities.

A growing body of rehabilitation research on people with advanced cancer demonstrates effects on function and independence.[19–26] These studies are largely exercise-based interventions.[22–26] Occupational therapy–based (OT-based) interventions bring a different approach to existing palliative care interventions by intervening more directly on the target population's everyday activity problems.[27] A key principle underpinning most OT-based interventions is a person-centred approach where the interventions are tailored to patient's priorities,[27] which is in accordance with palliative care principles.[28] To our knowledge, only two pilot randomised controlled trials (RCT)[29,30] and one underpowered full-scale RCT[31] have investigated OT-based interventions in people with advanced cancer. All three studies[29–31] included adaptive interventions delivered by OTs, that is, interventions that include intrinsic changes, like change of habits and behaviour, and/or extrinsic changes, for example, provision of assistive technology and home modification.[32] Overall, the studies[29–31] showed that delivering an adaptive intervention focused on everyday activities for people with advanced cancer was feasible, although two of the studies had significant problems with recruitment and attrition.[30,31] Due to the limited evidence of OT-based interventions in

people with advanced cancer, we developed the 'Cancer Home-Life Intervention'.[12]

This study evaluates the efficacy of the 'Cancer Home-Life Intervention' and usual care compared with usual care alone in people with advanced cancer living at home in relation to ADL performance, difficulty performing prioritised everyday activities, autonomy and participation, and HRQoL.

## Methods

### Trial design

This parallel group, superiority RCT with balanced randomisation (1:1) consecutively recruited participants from oncology units at Aarhus University Hospital (AUH), Denmark, and Odense University Hospital (OUH), Denmark, from February 2015 to October 2016. The Ethics Committee decided that no approval was required for this study (S-20122000-96). The study was approved by the Danish Data Protection Agency (FN 215-57-0008) and registered at ClinicalTrials.gov (NCT02356627). A previous article describes the details of the protocol.[12]

### Participants

Eligible participants were home-living adults (⩾18 years) diagnosed with advanced cancer by their responsible oncologist, had a World Health Organization (WHO) Performance Status (PS) 1–2 (see Appendix 1)[33] and lived at home or in sheltered living within a maximum radius of 60 km from AUH or on the island of Funen. Ineligible participants were living in a nursing home or hospice, were cognitively impaired or had insufficient Danish language skills. The enrolled participants provided written informed consent.

### Intervention and control

The 'Cancer Home-Life Intervention' is a tailored, OT-based, adaptive programme for people with advanced cancer delivered by OTs. It aims to enable people to perform and participate in the everyday activities at home that they prioritise but have difficulties performing (e.g. ADL, leisure, social activities) through application of one or more of the six components (Table 1), with component 1 being mandatory. The rationale of the intervention is to compensate for their functional limitations by providing the participant with adaptive strategies that have the potential to give people more energy to perform and participate in the everyday activities they prioritise. The adaptive components include intrinsic and extrinsic changes, like supporting them to prioritise time and to divide activities into smaller parts, teaching them strategies to use their body in a more efficient and safe manner, and providing assistive technology and home modifications. All components are delivered through instruction in and practice of the selected strategies. Each participant is offered 1–3 face-to-face home visits lasting max 120 min and 1–3 telephone contacts after the first intervention visit to reinforce intervention strategy use and resolve any emerging problems. The tailoring (which components and the number of components and home visits) is based on the participant's type of activity problems. For details, see the protocol and Table 1.[12]

Usual care comprised home-care, palliative care and/or rehabilitation that sometimes also involved OT as provided by the participants' home municipality.

### Procedures

Six intervention occupational therapists (I-OTs) performed the intervention. The I-OTs participated in a one-day workshop where they trained in performing the intervention with time to discuss the different parts of the intervention with the developers in order to standardise the delivery of the intervention. The I-OTs participated in three meetings during the study period to enhance the fidelity of the intervention. During delivery, the I-OTs monitored their fidelity to the intervention manual by reporting which components they provided to each participant.[12] Eight trained data-collection occupational therapists (D-OTs) collected the data from February 2015 to December 2016. They collected baseline (T1) and 12-week (T3) data in the participants' homes. Six-week (T2) data were collected using a postal questionnaire and telephone interview.

### Outcome measures

*ADL performance.* The Assessment of Motor and Process Skills (AMPS) is an observation-based instrument measuring the observed quality of ADL task performance. It has two domains: ADL motor ability and ADL process ability. Higher positive measures represent better ADL performance. Measures of ⩾0.3 logits on both indicate a clinically relevant change. ADL motor ability measures above 2.0 logits and ADL process ability measures above 1.0 logits represent competent ADL performance (no physical effort, efficient, safe and independent). The AMPS has demonstrated sound psychometric properties in terms of validity and reliability among people with cancer[34,35] and sensitivity to change in other diagnostic groups.[13]

*Difficulties performing the participants' prioritised everyday activities.* The Individually Prioritised Problem Assessment (IPPA) is a generic, structured interview–based instrument that is used to identify participants' prioritised everyday activities and the ease/difficulty participants encounter when performing them.[36] The participants prioritise up to seven activity problems and rate the

**Table 1.** Description of the 'Cancer Home-Life Intervention'.

| Intervention features | Intensity and content |
|---|---|
| Setting | Participant's home |
| Format | Individual |
| Intervention provider | Occupational therapist |
| Number of home visits | 1–3 |
| Intervention period | ⩽3 weeks |
| Time per visit | 60–120 min |
| Telephone follow-up | 1–3 |
| *Mandatory component* | |
| Component 1 | *Initial interview*<br>Identify prioritised everyday activity problems in the home environment. The I-OT and the participant schedule an intervention plan together.They select which of the five optional components that should be included, tailoring the intervention to the participant's needs with their prioritised everyday activities. |
| *Optional components* | |
| Component 2 | *Prioritisation of resources, energy and activities*<br>Instructing participant in energy conservation techniques, talking about time to rest during the day and delegating activities to family members or other people, for instance, so that participants can perform and participate in their prioritised everyday activities. |
| Component 3 | *Adaptation of activities*<br>Instructing participant in how to perform prioritised everyday activities in alternative ways according to symptom management, for example, by working in a seated position instead of standing, splitting tasks into actions, reordering actions and asking for assistance. |
| Component 4 | *Adaptation of posture and seating positioning*<br>Instructing participants and practising seated positioning and ergonomics when performing their prioritised everyday activities, for example, lifting techniques, how to obtain a good seating/standing position during activity and how to obtain a good resting position in bed or other places. |
| Component 5 | *Provision of assistive technology*<br>Selecting assistive devices for participants and instructing and practicing in using them when performing prioritised everyday activities, for example, mobility devices, devices for gardening, devices for handling cold objects. |
| Component 6 | *Modification of the physical home environment*<br>Providing home safety and home modification, for example, rearranging furniture or setting up handrails, and ensuring home safety. |

I-OT: intervention occupational therapist.

importance and difficulty of these problems. In this study, prioritised activity problems were limited to those in the home environment. IPPA scores range from 1 to 25, with a higher score indicating a greater degree of difficulty performing prioritised everyday activities. The IPPA has been found to be a responsive and valid instrument in elderly people.[37,38]

*Autonomy and participation.* The Danish version (IPA-DK) of the Impact on Participation and Autonomy Questionnaire (IPAQ) is a generic questionnaire used to identify person-perceived participation restrictions. It has five domains.[39] We used autonomy indoors, family roles and social relations subscales with scores ranging from 0–4, with 0 being no participation restrictions and 4 being perceived severe participation restrictions. The scores were dichotomised into no perceived restrictions (score 0 and 1) and perceived restrictions (scores 2, 3 and 4). The IPA-DK and IPAQ have demonstrated acceptable psychometric properties regarding validity, reliability and sensitivity.[40–43]

*HRQoL.* The European Organisation for Research and Treatment of Cancer Quality-of-Life Questionnaire Core 30 (EORTC QLQ C-30) is a cancer-specific questionnaire assessing HRQoL and consists of 15 scales.[44] We used the global health status/Quality of Life scale as an overall measure of HRQoL, with scores ranging from 0 to 100, where higher scores indicate better HRQoL.[44] The EORTC QLQ C-30 has been found to be a responsive, valid and reliable instrument among people with advanced cancer.[45,46]

## Primary outcome

- Change in ADL motor ability from T1–T3 measured with the AMPS.[13]

### Secondary outcomes

- Change in ADL process ability from T1–T3 measured with the AMPS;[13]
- Change in difficulties performing prioritised everyday activities from T1–T2 and from T1–T3 assessed with the IPPA;[36]
- Probability of no perceived participation restrictions within the domains autonomy indoors, family role and social relations at T2 and T3 assessed by the IPA-DK;[39]
- Change in HRQoL from T1–T2 and from T1–T3 assessed by the EORTC QLQ C-30.[44]

### Sample size

To identify a clinically relevant between-group change of 0.3 logits on the ADL motor ability, we needed to recruit 272 participants with an expected attrition of 32% ($N = 184$ would provide 80% power). Alpha was 5% and the standard deviation (SD) 0.727.[12]

### Randomisation and masking

After T1, the D-OTs randomised the participants to one of the two groups using online computer-generated randomisation with a fixed block size prepared by the Odense Patient Data Explorative Network that had no other study involvement.

Analyses were performed masked for the group allocation. The D-OTs were masked when collecting the outcome measures.

### Analyses

Descriptive data are presented with mean values and SD, median and interquartile range (IQR), or number and percent. For quantitative outcomes (AMPS, IPPA and EORTC QLQ C-30), change in the intervention group was compared with change in the control group[47] using multiple linear regression analyses. Analyses were adjusted for hospital.

Logistic regression analysis was performed comparing the odds ratio (OR) of not having perceived participation restrictions within the three IPA-DK domains. Between-group change and the OR were presented with 95% confidence intervals (CI).

Primary analyses were performed as complete case analysis, excluding participants with missing outcome measure values and with invalid AMPS data. Data were analysed according to original group allocation; and two sensitivity analyses were conducted to examine the robustness of the primary analyses:

1. Linear regression analysis adjusted for unbalanced variables at T1 between the groups.[12]
2. Mixed linear models to investigate change over time and between-group differences for quantitative outcomes.

$p$ values $\leqslant 0.05$ were considered statistically significant. Analyses were performed using STATA 14.

## Results

### Participants

Between 16 January 2015 and 28 September 2016, 522 people were invited to participate (Figure 1). Measures were completed at T1 by 242 participants who were randomised to intervention ($n = 121$) or control ($n = 121$). No significant differences for age ($p = 0.29$), gender ($p = 0.55$), WHO PS ($p = 0.65$) and primary cancer type ($p = 0.24$) were found between participants and those who declined participation.

Attrition was almost similar (intervention: 8.3% (T2) and 9.9% (T3)) versus control: 7.4% (T2) and 12.4% (T3)) with death and illness being the main causes. T3 (AMPS: $n = 1$ invalid) was completed by 191 participants (Figure 1). The number of people included was sufficient to reach the calculated sample size ($N = 184$).

The mean age for the study population was 67.91, slightly more women than men participated (124 (51.2%)), and the majority of the participants were living with a partner (167 (68.9%)). The most common primary cancer types were gastrointestinal (74 (30.6%)), lung (48 (19.8%)) and breast (37 (15.3%)). The mean ADL motor ability was 1.13 logits, namely, far below the competence cut-off ($<2.0$ logits), indicating safety risk and/or need for assistance during ADL performance. The mean ADL process ability was 0.84 logits, which is just below the competence cut-off ($<1.0$ logits). Participants encountered difficulties performing their prioritised everyday activities (mean score 14.26 on 1–25 scale) and had reduced HRQoL (mean score 58.51 on 0–100 scale). They reported almost no perceived participation restrictions within the three subdomains of the IPA-DK (Table 2).

We found the two groups comparable at baseline, but did see slightly more women in the control group. We therefore adjusted for gender in the sensitivity analyses.

### Delivered interventions

Eight participants declined the intervention (6.61%). The remainder of the intervention group received the mandatory component 1 (113 (93.4%)). The median number of delivered components was three. A total of 36 participants (29.8%) received more than one home visit, and 62 participants (51.2%) received at least one follow-up telephone contact (Table 3). Agreement between the D-OTs' estimate of group allocation and the actual allocation was

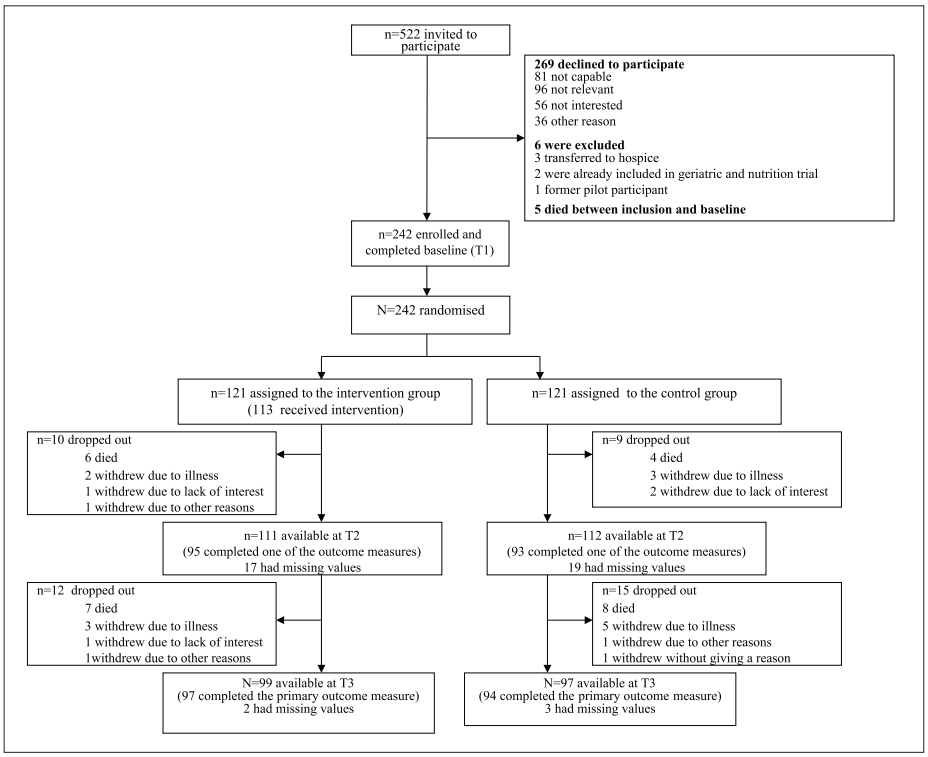


**Figure 1.** Flow chart

66.2% ($k = 0.32$ (95% CI: 0.21–0.44)), indicating weak agreement. Five participants (4.1%) in the control group received some element of OT from their local municipality during T1–T2 and two participants (1.7%) from T2–T3.

### *The primary outcome*

ADL motor ability decreased in both groups during T1–T3 (Figure 2(a)). The within-group change was small (intervention group: –0.14 logits (95% CI: –0.27 to 0.00)) (control group: –0.10 logits (95 CI: –0.24 to 0.05); Table 4) with the change in the intervention group being borderline significant. We observed no statistically significant effect of the 'Cancer Home-Life Intervention' on the primary outcome from T1–T3 (between-group mean change in ADL motor ability: –0.04 logits (95% CI: –0.23 to 0.15); $p = 0.69$; Table 4). Sensitivity analyses did not change the results.

### *Secondary outcomes*

Both groups' ADL process ability decreased during T1–T3 (Figure 2(b)). The two groups experienced statistically less difficulty performing their prioritised everyday activities over time (Table 4). Small within-group change was found concerning HRQoL, decreasing during T1–T2 and increasing during the last follow-up (Figure 2(d)). The probability of no perceived participation restrictions was high for both groups at both follow-ups. No statistically significant between-group differences were found (Table 4). Sensitivity analyses confirmed the results of no intervention effect.

## Discussion

This RCT evaluated the efficacy of the 'Cancer Home-Life Intervention' compared with usual care alone in people with advanced cancer living at home. We found no

**Table 2.** Participants' baseline characteristics ($N = 242$).

| | Study population ($N = 242$) | Intervention group ($n = 121$) | Control group ($n = 121$) |
|---|---|---|---|
| Age (years), mean (SD) | 67.91 (9.00) | 68.67 (8.64) | 67.16 (9.32) |
| Women, *n* (%) | 124 (51.2) | 54 (44.6) | 70 (57.9) |
| Hospital, *n* (%) | | | |
| AUH | 222 (91.7) | 111 (91.7) | 111 (91.7) |
| OUH | 20 (8.3) | 10 (8.3) | 10 (8.3) |
| Living alone, *n* (%) | 74 (30.7) | 33 (27.5) | 41 (33.9) |
| Missing, *n* (%) | 1 (0.4) | 1 (0.8) | 0 (0.00) |
| Type of residence, *n* (%) | | | |
| House | 168 (69.7) | 85 (70.8) | 83 (68.6) |
| Apartment | 57 (23.7) | 25 (20.8) | 32 (26.5) |
| Other | 16 (6.6) | 10 (8.3) | 6 (5.0) |
| Missing, *n* (%) | 1 (0.4) | 1 (0.8) | 0 (0.00) |
| Education, *n* (%) | | | |
| ⩽10 years | 64 (26.7) | 31 (25.8) | 33 (27.5) |
| 11–12 years | 63 (26.3) | 37 (30.8) | 26 (21.7) |
| >13 years | 113 (47.1) | 52 (43.3) | 61 (50.8) |
| Missing, *n* (%) | 2 (0.8) | 1 (0.8) | 1 (0.8) |
| Comorbidities, *n* (%) | | | |
| 0 | 52 (21.5) | 25 (21.6) | 27 (22.5) |
| 1–3 | 161 (66.5) | 79 (68.1) | 82 (68.3) |
| >3 | 23 (9.5) | 12 (10.3) | 11 (9.2) |
| Missing, *n* (%) | 6 (2.5) | 5 (4.1) | 1 (0.8) |
| Primary tumour site, *n* (%) | | | |
| Gastrointestinal | 74 (30.6) | 44 (36.4) | 30 (24.8) |
| Lung | 48 (19.8) | 22 (18.2) | 26 (21.5) |
| Breast | 37 (15.3) | 16 (13.2) | 21 (17.4) |
| Prostate | 30 (12.4) | 16 (13.2) | 14 (11.6) |
| Head and neck | 17 (7.0) | 10 (8.3) | 7 (5.8) |
| Bladder | 15 (6.2) | 6 (5.0) | 9 (7.4) |
| Gynaecological | 14 (5.8) | 2 (1.2) | 12 (9.9) |
| Other | 6 (2.5) | 5 (4.1) | 1 (0.8) |
| Missing, *n* (%) | 1 (0.4) | 0 (0.0) | 1 (0.8) |
| WHO Performance Status, *n* (%) | | | |
| 1 | 171 (71.0) | 81 (67.5) | 90 (74.4) |
| 2 | 70 (29.1) | 39 (32.5) | 31 (25.6) |
| Missing, *n* (%) | 1 (0.4) | 1 (0.8) | 0 (0.0) |
| ADL motor ability (AMPS), mean (SD)[a] | 1.13 (0.59) | 1.12 (0.58) | 1.14 (0.59) |
| Below competence cut-off, *n* (%)[b] | 230 (95.4) | 117 (97.5) | 113 (93.4) |
| Missing, *n* (%) | 1 (0.4) | 1 (0.8) | 0 (0.0) |
| ADL process ability (AMPS), mean (SD)[a] | 0.84 (0.39) | 0.85 (0.39) | 0.84 (0.38) |
| Below competence cut-off, *n* (%)[b] | 142 (58.9) | 71 (59.2) | 71 (58.7) |
| Missing, *n* (%) | 1 (0.4) | 1 (0.8) | 0 (0.0) |
| IPPA mean score (SD)[c,d] | 14.26 (4.06) | 14.16 (3.65) | 14.35 (4.45) |
| Missing, *n* (%) | 3 (1.2) | 0 (0.0) | 3 (3.3) |
| Number of activity problems, *n* (%) | | | |
| 0 | 64 (26.6) | 33 (27.5) | 31 (25.6) |
| 1–3 | 76 (31.5) | 35 (29.2) | 41 (33.9) |
| >3 | 101 (41.9) | 52 (43.3) | 49 (40.5) |
| Missing, *n* (%) | 1 (0.4) | 1 (0.8) | 0 (0.0) |
| HRQoL (QLQ-C30), mean (SD)[e,f] | 58.51 (21.98) | 57.64 (22.7) | 59.38 (21.4) |
| Missing, *n* (%) | 2 (0.8) | 1 (0.8) | 1 (0.8) |

*(Continued)*

**Table 2.** (Continued)

| | Study population ($N=242$) | Intervention group ($n=121$) | Control group ($n=121$) |
|---|---|---|---|
| Autonomy indoor (IPA-DK), median (IQR)[g] | 0 (0–1) | 0 (0–1) | 0 (0–1) |
| Missing, *n* (%) | 2 (0.8) | 1 (0.8) | 1 (0.8) |
| Family role (IPA-DK), median (IQR)[g] | 1 (0–2) | 1 (0–2) | 1 (0–2) |
| Missing, *n* (%) | 3 (1.2) | 1 (0.8) | 2 (1.7) |
| Social relations (IPA-DK), median (IQR)[g] | 0 (0–1) | 0 (0–1) | 0 (0–0) |
| Missing, *n* (%) | 5 (2.1) | 3 (2.5) | 2 (1.7) |

SD: standard deviation; AUH: Aarhus University Hospital; OUH: Odense University Hospital; WHO: World Health Organization; ADL: activities of daily living; AMPS: Assessment of Motor and Process Skills; IPPA: Individually Prioritised Problem Assessment; HRQoL: health-related quality of life; QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of life C-30; IPA-DK: The Danish Version (IPA-DK) of the Impact on Participation and Autonomy Questionnaire (IPAQ); IQR: interquartile range.
[a]Higher positive measures represent a greater degree of ADL ability.
[b]Below competent cut-off on the ADL motor ability (<2.0 logits) and the ADL process ability (<1.0 logits).
[c]The IPPA score ranges from 1 to 25, with higher scores indicating a greater degree of difficulty performing prioritised everyday activities.
[d]Only includes participants with at least one prioritised activity problem (intervention group: $n=87$ and control group: $n=90$).
[e]The global health status/quality of life scale from the EORTC QLQ C-30 is used to assess HRQoL.
[f]The HRQoL ranges from 0 to 100, with higher scores indicating a greater degree of HRQoL.
[g]The IPA-DK ranges from 0 to 4, with 0 being no perceived participation restrictions and 4 being severe perceived participation restrictions.

**Table 3.** Components from the 'Cancer Home-Life Intervention' delivered to the participants in the intervention group ($N=121$)[a] and total number of home visits, telephone follow-up contacts and time.

| The 'Cancer Home-Life Intervention' | |
|---|---|
| Components given by the intervention occupational therapist, *n* (%) | |
| 1. Interview | 113 (93.4) |
| 2. Prioritise resources, energy and activities | 73 (60.3) |
| 3. Adaptation of activities | 70 (57.9) |
| 4. Adaptation of posture and seated positioning | 37 (30.6) |
| 5. Assistive technology | 65 (53.7) |
| 6. Modification of the physical home environment | 11 (9.1) |
| Number of components per participant, median (IQR) | |
| Number | 3 (2–4) |
| Home visits, *n* (%) | |
| First home visit | 113 (93.4) |
| Second home visit | 32 (26.4) |
| Third home visit | 4 (3.3) |
| Time, median minutes (IQR) | |
| First home visit | 105 (90–120) |
| Second home visit | 45 (30–75) |
| Third home visit | 45 (22.5–75) |
| Telephone follow-up, *n* (%) | |
| No follow-up telephone contact | 13 (10.7) |
| First follow-up telephone contact | 62 (51.2) |
| Second follow-up telephone contact | 39 (32.2) |
| Third follow-up telephone contact | 7 (5.8) |

IQR: interquartile range.
[a]Eight participants did not want to receive the intervention.

statistically significant effect of the OT-based intervention (Table 4).

Overall, our trial demonstrates high internal validity with limited and equal attrition between the groups, blinded assessors, sufficient statistical power and successfully performed randomisation. Below we discuss several aspects that need to be considered before one hastily concludes that OT-based interventions has no effect in people with advanced cancer.

### *Intervention intensity*

The delivered 'Cancer Home-Life Intervention' was tailored and adjusted to the participants. In this study, this resulted in the intervention mainly encompassing three components, most of which were used during one home visit (median minutes = 105) and one telephone contact over a 3-week time span (Table 3). One explanation for why the 'Cancer Home-Life Intervention' showed no effect in this study may be that the intensity of the intervention was too low. An important question in this respect is what is a minimum of OT-based intervention required to instil change. To our knowledge, no clear cut-off of the minimum intensity required to instil change exists.[48] A systematic review[49] found short-term effects on ADL and prioritised everyday activities of low intensity OT-based interventions in older people delivered over 2.5–6 months with a mean intensity varying from 0.8 to 3.4 intervention sessions per month.[49] The literature on behavioural change would argue that one home visit and one telephone contact is not enough to change strategies and achieve change, as this requires more therapeutic support over longer periods

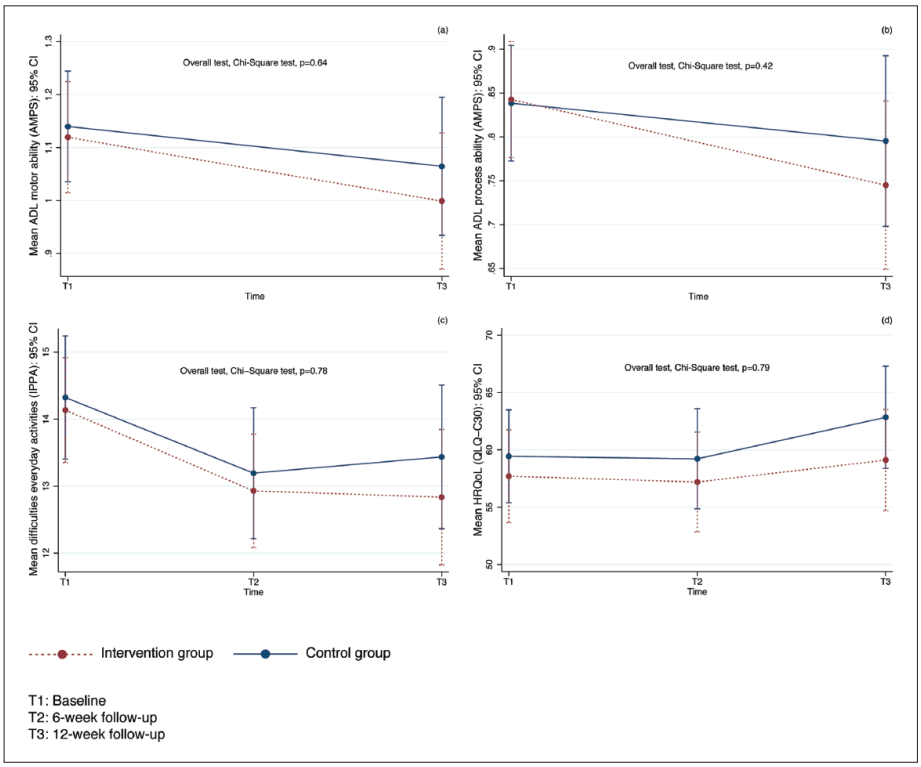


**Figure 2.** Change over time and between-group differences. ADL=Activities of Daily Living; AMPS=Assessment of Motor and Process Skills; IPPA=Individually Prioritised Problem Assessment; HRQoL=Health-related Quality of Life; QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire C-30.

of time.[50] However, a telephone-delivered problem-solving OT-based intervention by Hegel et al.[29] lasted on average 106 min, and they found effect on function, HRQoL and emotional state. This amount of time almost equals the time used in our intervention. When we designed the trial, we decided that 1–3 visit would be enough – partly based on the trial by Hegel et al.[29] Moreover, we had expected that most participants would receive more than one visit. However, based on our results and the knowledge of behaviour change theory,[50] one may consider if we should have delivered the intervention over a longer period of time and increased the intensity.

### *Feasibility*

We did not conduct a full feasibility study before the trial as advocated by the Medical Research Council,[51] since our cross-sectional study gave us knowledge about relevant outcomes, and we had sufficient information for estimating sample size, recruitment and so on.[12] Furthermore, we had explored the acceptability and usefulness of the intervention in four people with advanced cancer, which showed that they definitely would value such an intervention.[12] Still, a full feasibility study could have given us important information about required intervention intensity and intervention relevance.

### *Outcomes*

Many people with advanced cancer face serious difficulties with ADL,[5,6,8,9] which motivated our choice of ADL as the primary trial outcome.[8] However, they also experience difficulties in other areas at home, such as leisure and

**Table 4.** Mean change in primary outcome and secondary outcomes from baseline (T1) to six- (T2) and 12-week follow-up (T3) and odds ratio for no perceived participation restrictions; complete case analysis.

| Outcomes | *n* | Intervention group | *n* | Control group | Between-group mean change (95% CI) | *p* value |
|---|---|---|---|---|---|---|
| | | Mean change | | Mean change | | |
| *AMPS* | | | | | | |
| ADL motor ability T1–T3[a,b,c,d] | 97 | −0.14 (–0.27 to 0.00) | 94 | −0.10 (–0.24 to 0.05) | −0.04 (–0.23 to 0.15) | 0.69 |
| ADL process ability T1–T3[a,b,c,d] | 97 | −0.10 (–0.20 to –0.01) | 94 | −0.04 (–0.14 to 0.06) | −0.06 (–0.20 to 0.07) | 0.37 |
| *IPPA* | | | | | | |
| IPPA score T1–T2[c,d,e] | 67 | −1.27 (–2.01 to –0.53) | 65 | −1.16 (–1.91 to –0.41) | −0.11 (–1.17 to 0.95) | 0.83 |
| IPPA score T1–T3[c,d,e] | 62 | −1.38 (–2.35 to –0.40) | 63 | −1.03 (–2.00 to –0.05) | −0.35 (–1.71 to 1.01) | 0.61 |
| *EORTC QLQ C-30* | | | | | | |
| HRQoL T1–T2[c,d,f,g] | 94 | −1.40 (–5.49 to 2.68) | 93 | −1.19 (–5.39 to 3.01) | −0.21 (–5.97 to 5.54) | 0.94 |
| HRQoL T1–T3[c,d,f,g] | 93 | 1.50 (–2.97 to 5.97) | 90 | 3.11 (–1.52 to 7.74) | −1.61 (–7.95 to 4.73) | 0.62 |
| Outcomes | *n* | Intervention group | *n* | Control group | Odds ratio for no perceived participation restrictions (95% CI) | *p* value |
| | | Odds[i] | | Odds[j] | | |
| *IPA-DK*[h] | | | | | | |
| Autonomy Indoor T2 | 95 | 7.64 (4.07 to 14.32) | 91 | 6.00 (3.36 to 10.79) | 1.27 (0.54 to 3.02)[j,k] | 0.59 |
| Autonomy Indoor T3 | 89 | 8.89 (4.46 to 17.71) | 87 | 8.67 (4.35 to 17.28) | 1.03 (0.39 to 2.75)[j,k] | 0.95 |
| Family role T2 | 95 | 1.21 (0.81 to 1.81) | 91 | 1.39 (0.92 to 2.12) | 0.83 (0.46 to 1.50)[j,k] | 0.54 |
| Family role T3 | 89 | 1.70 (1.10 to 2.61) | 87 | 1.56 (1.01 to 2.40) | 1.08 (0.59 to 1.99)[j,k] | 0.81 |
| Social relations T2 | 95 | 18.00 (7.31 to 44.30) | 89 | 13.83 (6.04 to 31.68) | 1.22 (0.35 to 4.21)[j,k] | 0.75 |
| Social relations T3 | 89 | 11.71 (5.41 to 25.34) | 87 | 13.50 (5.89 to 30.94) | 0.86 (0.28 to 2.69)[j,k] | 0.80 |

AMPS: Assessment of Motor and Process Skills; ADL: activities of daily living; IPPA: Individually Prioritised Problem Assessment; IPA-DK: The Danish Version (IPA-DK) of the Impact on Participation and Autonomy Questionnaire (IPAQ); EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire C-30; HRQoL: Health-related Quality of Life.
[a]Higher positive measures represent a greater degree of ADL ability.
[b]Exponential transformation of the difference between groups did not change the results.
[c]Multiple linear regression adjusted for hospital. The estimates are shown in the table.
[d]Multiple linear regression adding gender in the model did not change the results and are therefore not shown in table.
[e]The IPPA score ranges from 1 to 25, with higher scores indicating a greater degree of difficulty performing prioritised everyday activities.
[f]The global health status/quality of life scale from the EORTC QLQ C-30 is used to assess HRQoL.
[g]The HRQoL ranges from 0 to 100, with higher scores indicating a greater degree of HRQoL.
[h]The IPA-DK were dichotomised into 'no perceived participation restrictions' and 'perceived participation restrictions'.
[i]Odds for no perceived participation restrictions.
[j]Logistic regression adjusted for hospital. The estimates are shown in the table.
[k]Logistic regression adding gender in the model did not change the results and are therefore not shown in table.

creative activities,[7] which our intervention was also designed to solve.

Selecting outcome measures that capture the essence of an intervention is challenging, especially in people with advanced cancer with complex and diverse needs.[6] Outcome measures in palliative care need to be psychometrically robust and sensitive to capture change over time.[52] Sensitivity to change is particularly important when evaluating intervention effect. We selected the AMPS as an ADL measure because it is highly sensitive[13] and more sensitive in oncology patients than other tools.[53] However, the 'Cancer Home-Life Intervention' targeted participants' prioritised everyday activity problems which do not always include ADL. This could have affected the causal connection between the 'Cancer Home-Life Intervention' and the AMPS, which may have been too narrow in scope.

### *Recruitment*

Recruiting the most relevant study population is another challenge. We may have included individuals without the most urgent need for the intervention since 26.6% of the participants reported no activity problems (Table 2). We cannot rule out that this may have biased the results towards the null value as these people probably received a smaller amount of interventions. Over two-thirds of the participants had a WHO PS1, meaning that we mostly recruited better functioning people with advanced cancer. People with WHO PS1 still have difficulties performing physically strenuous activities but may have less difficulties performing ADL. However, their ADL ability measured with the AMPS clearly indicated need of assistance to live in the community. Nevertheless, this issue raises the

question whether we have identified the most appropriate participants for an OT-based intervention since so many had no prioritised activity problem. A solution could have been to use self-reported activity problems as an inclusion criterion.

### *What this study adds*

This study is the first full-scale, adequately powered RCT investigating the efficacy of an OT-based intervention in people with advanced cancer.[54,55] Our study demonstrates that it is feasible to conduct a full-scale RCT in this vulnerable group of people and that the majority of them want and need OT-based interventions that support their everyday activities at home. This underlines that even though our RCT produced no evidence supporting the benefits of the present OT-based intervention, research and clinical practice in palliative care still need to focus on how to enable everyday activities in people with advanced cancer, helping them to live their lives as fully as possible.

## Conclusion

The 'Cancer Home-Life Intervention', delivered mostly through a single home visit and a single follow-up telephone contact, was not effective in maintaining or improving participants' everyday activities and HRQoL. Future studies should pay even more attention to intervention development, minimal intervention 'dose' believed to make a change and feasibility testing.

### Acknowledgements

The authors thank the participants, the employees from the hospitals and the OTs. They also thank our advisory board: Professor Malcolm Cutchin, Professor Anders Bonde Jensen, Professor Jens Søndergaard and Associate Professor Eva Ejlersen Wæhrens.

### Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

### Funding

The author(s) disclosed receipt of the following financial support for the research, authorship and/or publication of this article: The TrygFonden and the Danish Cancer Society (R53-A2783), the University of Southern Denmark, the Danish Association of Occupational Therapists (FF 2 14 – 3), and the Region of Southern Denmark (15/23775) funded the study.

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**Appendix 1.** Description of the World Health Organization performance status.

| Grade | Explanation of activity |
|---|---|
| 0 | Fully active, able to carry on all pre-disease performance without restriction |
| 1 | Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, for example, light housework, office work |
| 2 | Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours |
| 3 | Capable of only limited self-care, confined to bed or chair more than 50% of waking hours |
| 4 | Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair |
| 5 | Dead |

# Paper III

# Subgroup effects of occupational therapy-based intervention for people with advanced cancer

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**Abstract**

**Background**: Many people with advanced cancer have decreased ability to perform activities of daily living (ADL). We recently performed a randomised, controlled trial (RCT) assessing the efficacy of an occupational therapy-based program, the 'Cancer Home-Life Intervention', in people with advanced cancer (N=242) and found no overall effects on ADL ability. However, heterogeneity of treatment effect may disguise subgroup differences.

**Objective**: To investigate whether subgroups of people with advanced cancer gain positive effects from the 'Cancer Home-Life Intervention' on ADL ability.

**Material and method**: An exploratory subgroup analysis including 191 participants from a RCT. The outcome was *ADL motor ability* measured by the Assessment of Motor and Process Skills (AMPS). Subgroups were defined by age, gender, years of education, type of primary tumour, functional level, and activity problems.

**Results**: The 'Cancer Home-Life Intervention' had no statistically significant effect in the six subgroups. Modifying effects of age (0.30 [95% CI: -0.05 to 0.64]) and gender (0.23 [95% CI: -0.11 to 0.57]) were not found.

**Conclusion**: There were no subgroup effects of the 'Cancer Home-Life Intervention'on ADL motor ability. Some indications suggest greater effects for those aged below 69 years; however, this result should be interpreted with caution.

Activities of Daily Living; Neoplasms; Occupational Therapy; Randomised Controlled Trial; Moderator Variables

## Introduction

Studies show that between 43%-74% of those with advanced cancer have decreased ability to perform activities of daily living (ADL) (1-3). Problems with ADL may contribute to loss of independence (4) and have unfavourable consequences for individuals' health-related quality of life (5). ADL encompass the ability to perform personal ADL (PADL) related to self-care (e.g. eating and dressing) and instrumental ADL (IADL) related to home maintenance (cooking, housework, and shopping) (4). One of the aims of occupational therapy-based (OT-based) interventions is to support people to perform their ADL (6). However, very little is known about efficacious OT-based interventions for people with advanced cancer (7-9). We therefore performed a randomised, controlled trial (RCT) (10) to assess the efficacy of a tailored, adaptive, OT-based program, the 'Cancer Home-Life Intervention', compared with usual care received by people with advanced cancer living at home. The 'Cancer Home-Life Intervention' is delivered by an occupational therapist (OT) and has six intervention components: 1) a mandatory initial interview that addresses everyday activity problems and needs. Based on this interview, one or more of the following components are selected by the OT and the participant: 2) prioritisation of resources, energy, and activities; 3) adaptation of activities; 4) adaptation of posture and seating positioning; 5) provision of assistive technology; and 6) modification of the physical home environment (10, 11).

In total, 121 participants were randomised into the intervention group. Besides receiving the mandatory component 1, intervention participants primarily received component 2 (n = 51; 42.2%), component 3 (n = 35; 28.9%), and component 5 (n = 46; 38.0%). The intervention was delivered mainly during a single home visit (typically lasting 105 minutes) and a single follow-up telephone contact (10). The 'Cancer Home-Life Intervention' showed no effect compared with usual care with respect to ADL motor ability, which was the primary outcome, measured by means of the Assessment of Motor and Process Skills (AMPS) from baseline (T1) to follow-up at 12 weeks (T2) (-0.04 logits [95% CI:-0.23 to 0.15], $p = 0.69$) (10). However, since this estimate is the overall mean effect and the trial included a heterogeneous population, the effect may vary in subgroups of people with advanced cancer (12). In our study protocol, we outlined four subgroups to be included in a subgroup analysis (11) – age, gender, primary tumour, and performance status – as research suggests that these factors

are associated with ADL or physical functioning (13-17). These factors may also be associated with a different treatment response to the 'Cancer Home-Life Intervention'. To our knowledge, only two RCTs have investigated subgroup effects of OT-based interventions (18, 19). Gitlin et al. (2008) conducted a subgroup analysis of an RCT to investigate the effectiveness of an OT-based intervention in community-living older adults and found effects on ADL in three subgroups according to age, gender, and level of education (Gitlin et al., 2008). The applied OT-based intervention (20) had five OT sessions involving education, problem-solving, home modification, and energy conservation training. Sheffield et al. (2012) also conducted a subgroup analysis in their RCT to examine the effectiveness of an OT-based intervention similar to that of Gitlin et al. in people aged 65 and older. However, they found no subgroup effects on ADL (19).

Identifying subgroups with advanced cancer that may benefit from the 'Cancer Home-Life Intervention' can help clinical practitioners and OT researchers target those who would benefit most from the intervention. The purpose of the present study was therefore to explore whether we could identify subgroups of people with advanced cancer who gained positive effects from the 'Cancer Home-Life Intervention' with respect to ADL motor ability at the 12-week follow-up.

## Methods

This study was an exploratory subgroup analysis of data from a rater-blinded, two-armed RCT. The study protocol and the main results from the RCT have been published previously (10, 11).

### *The RCT evaluating the efficacy of the 'Cancer Home-Life Intervention'*

In total, 242 adults (≥18 years) who lived at home were recruited from two Danish hospitals from February 2015 to October 2016 (10). The sample in the present study comprised 191 participants who had completed the AMPS at T1 and T2. They had been diagnosed with advanced cancer and had a functional level of 1-2 on the World Health Organization (WHO) performance status (PS). WHO PS1 stands for those who are ambulatory and able to manage daily activities of a lighter nature, but are restricted in performing physically demanding activities. WHO PS2 denotes people who are ambulatory and able to manage self-care, but are restricted in performing work activities

(21). An additional inclusion criterion was that the participants lived at home or in sheltered accommodation. Patients were excluded if they lived in a nursing home or hospice, had cognitive impairments, or lacked the proficiency in Danish required for them to complete questionnaires and participate in interviews.

The ADL ability of the included participants was measured at T1 and T2 by eight blinded data-collection occupational therapists. After T1, participants were randomised to the intervention group (n=121) or the control group (n=121).

***Outcome***

ADL motor ability was measured by the AMPS. The AMPS is a standardised, observation-based, occupational therapy instrument that reflects two domains: ADL motor ability and ADL process ability (4). ADL motor ability measures are converted by Rasch-based computer-scoring software adjusting for rater severity, ADL task challenge, and skill item difficulty. Higher positive measures represent better ADL ability. ADL motor ability evaluates the amount of physical effort, clumsiness, and/or fatigue a person demonstrates during ADL task performance. A change of ≥0.3 logits indicates a clinically relevant change (4). The AMPS is found to be a valid and reliable instrument for people with advanced cancer (22, 23) and has also demonstrated good responsiveness in people with other diseases (4).

***Subgroups***

The subgroups were selected *a priori* as described in the trial protocol (11) according to gender, age, primary tumour, and WHO PS. Two variables were chosen after the data collection was completed: having activity problem(s) and years of education. This post-rationalisation was done for two reasons. First, 28% of the participants in the RCT (10) reported not having any activity problems. This may indicate that these individuals had less need for an OT-based intervention and were thus less likely to benefit from the intervention. Second, we included educational level, since Gitlin et al. (2008) found that those with less education benefited more from their OT-based intervention on ADL than did those with a longer education (18).

The subgroups were categorised as follows: *gender* (men versus women), *age* (<69 years versus ≥69 years, as 69 years was the median value), *primary tumour* (lung, head and neck, gynaecological, prostate, breast, gastrointestinal, bladder, and

other), *functional level* (WHO PS1 versus WHO PS2), *years of education* (≤10 years, 11-12 years, and ≥13 years), and *activity problems* (yes versus no).

Age and gender were registered using a study-specific questionnaire. Hospital nurses at two hospitals collected information about the participants' primary tumour from the responsible oncologist and rated the participants' WHO PS. Activity problems were assessed by the data-collection occupational therapists who used the Individually Prioritised Problems Assessment (IPPA) instrument. The IPPA is a self-report interview-based instrument where a person identifies up to seven activity problems that need solving (24-26). Information on educational level was collected using the study-specific questionnaire. All six variables were collected either before or at T1.

***Statistical analysis***

ADL motor ability at T1 and T2 are presented with mean values and standard deviation (SD) in the intervention group and in the control group, divided into six subgroups. Between-group mean changes were calculated for each subgroup with 95% confidence intervals (95% CI). A multiple regression analysis (27) was performed with ADL motor ability at T2 as the dependent variable, and treatment (intervention versus control), baseline ADL motor ability, gender, age, years of education, and activity problems as predictors. Regression coefficients for each predictor were estimated with 95% CI, and p values were reported. Interaction terms were then added to the regression analysis between the treatment and the selected modifiers (age and gender). Functional level and primary tumour were not included in the regression analysis for two reasons. Firstly, there was collinearity between baseline ADL motor and functional level in the model (28). Secondly, the size of the primary tumour subgroups were too small to be included in the model. Only age and gender were selected in the interaction test since these characteristics seem to be the most important modifiers (18, 29). Furthermore, research consistently shows significant age and gender ADL differences (13, 16, 17). A statistically significant interaction was tested by a Wald test (27). Model assumptions were investigated by QQ plot and histogram. A p value of 0.05 was considered statistically significant, and all analyses were performed using Stata 14.

***Ethics***

The Danish Regional Committees on Health Research Ethics considered approval not to be required (S-20122000-96). The Danish Data Protection Agency (FN 215-57-0008)

approved the study. All included participants provided oral and written informed consent and were informed that participation in the study was voluntary and that they could withdraw at any time. The trial was registered at www.controlled-trials.com/ClinicalTrials.gov NCT02356627.

## Results

Table 1 shows the T1 mean ADL motor ability and T2 mean ADL motor ability in the intervention group and the control group, stratified for each subgroup. The between-group mean change for the subgroups is also shown in Table 1. In the six subgroups, the mean ADL motor ability changes from T1 to T2 for both treatment groups were approximately normally distributed. Overall, the between-group mean change in the six subgroups was small, all confidence intervals included 0 and the estimates were generally below the threshold of a clinically relevant difference (≥0.3 logits) (4) (see Table 1). For instance, in those aged <69 years, the T1 ADL motor ability was 1.19 logits in the intervention group and 1.33 logits in the control group. During the 12-week follow-up, ADL motor ability decreased to 1.12 logits in the intervention group and 1.08 logits in the control group. The intervention group therefore decreased less than the control group (0.18 logits [95% CI:-0.09 to 0.45]), although this was not statistically significant, as 0 was included in the 95% CI (see Table 1).

[Insert Table 1]

The adjusted regression analysis with interaction terms is shown in Table 2. All model assumptions were fulfilled. The statistically significant predictors of T2 ADL motor ability were baseline ADL motor ability (0.48 logits [95% CI:0.32 to 0.64], $p$=<0.000) and gender (-0.24 logits [95% CI:-0.42 to -0.06], $p$=0.01). Gender and age did not statistically significantly modify the effects of the treatment on T2 ADL motor ability (see Table 2). We did, however, observe a tendency for interaction effect by age group, as the 95% CI tended to be in the positive direction with 0.64 logits in the upper end (0.30 logits [95% CI:-0.05 to 0.64], $p$=0.09).

[Insert Table 2]

## Discussion

The aim of the present exploratory study was to identify subgroups with advanced cancer who may have gained positive effects from the 'Cancer Home-Life Intervention' regarding ADL motor ability. Overall, we found that the intervention had no effects in any of the investigated subgroups. Men compared with women and younger participants

(<69 years) compared with older participants (≥69 years) did not respond differently in ADL motor ability after the intervention. We did, however, observe some indications of greater effects of the 'Cancer Home-Life Intervention' amongst younger participants.

Previous studies investigating subgroup effects of an OT-based intervention have focused on older adults living in the community (18, 19). Only the study by Gitlin et al. (2008) found subgroup effects on ADL. They showed that their OT-based intervention had greater effects on ADL for individuals aged ≥80 (18). This is contrary to our findings of greater effects for those aged <69 years. The two study populations are, however, not immediately comparable since people with advanced cancer live with a life-threatening illness and often experience fluctuating symptoms and problems (14). Furthermore, Gitlin et al. (2008) included individuals only aged ≥70 years, and thus had no younger group as a frame of reference (18).

We did two post-hoc analyses to investigate the robustness of our results regarding the possible influence of age on ADL motor ability. First, we wanted to challenge the indication of greater effects for the younger group by setting an even lower age cut-off (>60 years versus ≤60 years). Second, when dichotomising age, statistical power is lost, and therefore we entered age as a continuous covariate in the regression model. These analyses did not change the indication of greater effects in the younger group or the non-statistically significant results. Even though age did not moderate the effect of the 'Cancer Home-Life Intervention' statistically, participants aged <69 years seemed to benefit more than those aged ≥69 years. This result may be partly explained by the fact that the younger group have greater unmet needs (30), and may therefore be more receptive to applying the components of the intervention into their daily life at home. However, our trial may be underpowered to detect statistically significant subgroup effects or interactions, and the results should therefore be interpreted cautiously.

***Methodological considerations***

With respect to general recommendations for conducting subgroup analysis (31), our study has several strengths. Four subgroups were chosen in the design phase of the RCT with all variables being collected before or at the time of randomisation. We investigated effects on the primary trial outcome, ADL motor ability, as research shows that people with advanced cancer demonstrate increased clumsiness or physical effort or

inefficiency during ADL task performance (2). In the present study, we studied only one outcome, the primary trial outcome, as recommended (31). The AMPS data were collected by trained and calibrated occupational therapists, and data quality was validated during the entire study period by the Center for Innovative OT Solutions.

The study has two main limitations: 1) the effect of randomisation no longer works when stratifying populations into subgroups, and the participants may differ in other aspects than the delivered intervention; and 2) our sample size calculation was not powered to detect a clinically significant interaction (4, 11). This means that our indication of greater effect in participants aged <69 years may be attributable to other causes than age alone. Furthermore, the lack of power causes wide CIs, and estimates are therefore less likely to reach statistical significance.

The 'Cancer Home-Life Intervention' showed no effects in the main RCT (10) or in the present exploratory subgroup study. We need more knowledge about why the 'Cancer Home-Life Intervention' was not effective. The Medical Research Council recommends performing process evaluation to assess the fidelity and implementation of interventions, and which mechanisms of impact are at stake when trying to produce change through an intervention (32). In line with these recommendations, we are currently conducting a process evaluation of the RCT.

***Implications for Occupational Therapy Practice and research***

The purpose of subgroup analysis in an RCT is to identify groups of people that may respond differentially to an intervention (12).

- Our results are useful to OT practitioners and OT researchers as they show the importance of being aware of the possible influence of age on ADL ability in an OT-based intervention like the 'Cancer Home-Life Intervention'.
- This kind of knowledge is useful when planning future RCT studies that investigate the effectiveness of OT-based interventions, where it may also be relevant to investigate different age effects of an intervention.
- The present OT-based intervention is the largest RCT so far performed in people with advanced cancer, (33, 34) and indicates the potential usefulness of conducting subgroup analyses of future OT-based interventions.

## Conclusion

This is the first study to investigate subgroup effects of an OT-based intervention in people with advanced cancer. The 'Cancer-Home Life Intervention' had no statistically significant effects in subgroups defined by gender, age, years of education, type of primary tumor, extent of functional limitations, or having activity problems or not. No modifying effects of age and gender were found. There was a tendency towards greater effects in participants aged <69 years, but this result should be interpreted with caution and viewed as hypothesis-generating rather than be used to set guidelines for practice.

## Acknowledgement

We wish to thank all the participants who took part in the study, the OTs, and statistician and Professor Jakob Hjelmborg, University Southern Denmark, for statistical consultancy on the analyses. The trial was supported financially by TrygFonden, the Danish Cancer Society (R53-A2783), the University of Southern Denmark, the Danish Association of Occupational Therapists (FF 2 14 – 3), and the Region of Southern Denmark (15/23775).

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Table 1. Mean ADL motor ability in the intervention group andcontrol group and subgroup differences from baseline to 12-week follow-up

| | T1 mean ADL motor ability (SD) | | T2 mean ADL motor ability (SD) | | Between-group mean change[a] (95% CI) |
|---|---|---|---|---|---|
| Subgroups | Intervention group | Control group | Intervention group | Control group | |
| **Treatment (n=191)** | | | | | |
| Intervention group (n=97) | 1.16 (0.58) | - | 1.01 (0.69) | - | - |
| Control group (n=94) | - | 1.21 (0.58) | - | 1.10 (0.61) | |
| **Age (n=191)** | | | | | |
| <69 (n=95) | 1.19 (0.56) | 1.33 (0.57) | 1.12 (0.52) | 1.08 (0.75) | 0.18 (-0.09 to 0.45) |
| ≥69 (n=96) | 1.13 (0.59) | 1.08 (0.58) | 0.91 (0.82) | 1.11 (0.44) | -0.25 (-0.53 to 0.03) |
| **Gender (n=191)** | | | | | |
| Women (102) | 1.05 (0.64) | 1.17 (0.61) | 1.15 (0.40) | 1.14 (0.61) | 0.13 (-0.10. to 0.37) |
| Men (n=89) | 1.26 (0.49) | 1.26 (0.54) | 0.88 (0.87) | 1.04 (0.62) | -0.16 (-0.46 to 0.15) |
| **Education (n=190)** | | | | | |
| ≤10 years (n=50) | 1.15 (0.68) | 1.09 (0.58) | 0.95 (0.94) | 1.16 (0.42) | -0.27 (-0.73 to 0.19) |
| 11-12 years (n=52) | 1.21 (0.42) | 1.16 (0.53) | 0.94 (0.69) | 0.99 (0.61) | -0.10 (-0.48 to 0.28) |
| ≥13 years (n=88) | 1.12 (0.62) | 1.30 (0.59) | 1.12 (0.47) | 1.11 (0.70) | 0.19 (-0.07 to 0.44) |
| **Primary tumor (n=190)** | | | | | |
| Lung (n=36) | 1.21 (0.44) | 1.08 (0.61) | 1.05 (0.60) | 0.85 (0.78) | 0.07 (-0.49 to 0.64) |
| Head and Neck (n=11) | 0.90 (0.56) | 1.06 (0.94) | 0.25 (1.14) | 0.82 (1.16) | -0.41 (-1.90 to 1.08) |
| Gynecological (n=9) | NA | 1.44 (0.32) | NA | 1.41 (0.35) | NA |
| Prostate (n=25) | 1.29 (0.41) | 1.34 (0.45) | 1.10 (0.48) | 1.17 (0.68) | -0.02 (-0.48 to 0.42) |
| Breast (n=32) | 0.91 (0.41) | 1.03 (0.65) | 1.03 (0.33) | 1.08 (0.43) | 0.07 (-0.31 to 0.44) |
| Gastrointestinal (n=61) | 1.32 (0.59) | 1.44 (0.51) | 1.07 (0.81) | 1.30 (0.41) | -0.11 (-0.47 to 0.26) |
| Bladder (n=12) | 0.64 (1.00) | 1.01 (0.34) | 0.98 (0.50) | 0.97 (0.39) | 0.38 (-0.41 to 1.18) |
| Other (n=4) | 0.95 (0.79) | NA | 1.15 (0.53) | NA | NA |
| **Functional level (n=190)** | | | | | |
| PS1 (n=139) | 1.28 (0.44) | 1.32 (0.51) | 1.12 (0.66) | 1.13 (0.61) | 0.03 (-0.20 to 0.24) |
| PS2 (n=51) | 0.88 (0.75) | 0.83 (0.64) | 0.78 (0.74) | 0.97 (0.62) | -0.24 (-0.65 to 0.18) |
| **Activity problems (n=191)** | | | | | |
| No (n=57) | 1.47 (0.38) | 1.45 (0.43) | 1.11 (0.74) | 1.20 (0.44) | -0.11 (-0.42 to 0.19) |
| Yes (n=134) | 1.02 (0.59) | 1.11 (0.61) | 0.97 (0.67) | 1.05 (0.67) | 0.01 (-0.20 to 0.24) |

ADL=Activities of Daily Living
T1=Baseline
T2=12-week follow-up
[a] A change of ≥0.3 logits in ADL motor ability indicates a clinically relevant change.

Tabel 2. Linear regression model investigating predictors for ADL motor ability and interaction of age and gender

| Predictors | Adjusted mean ADL motor ability at T2[ab] [95% CI] | P values | Interaction with treament group[ab] [95% CI] | P of Interaction |
|---|---|---|---|---|
| **Treatment** | | | | |
| Control group (n=94) | Ref. | | | |
| Intervention group (n=97) | -0.02 [-0.20 to 0.15] | 0.82 | | |
| **Baseline ADL motor ability** | 0.48 [0.32 to 0.64] | <0.000 | | |
| **Age** | | | 0.30 [-0.05 to 0.64] | 0.09 |
| Age <69 (n=95) | Ref. | | | |
| Age ≥69 (n=96) | -0.03 [-0.21 to 0.15] | 0.76 | | |
| **Gender** | | | 0.23 [-0.11 to 0.57] | 0.19 |
| Women (n=101) | Ref | | | |
| Men (n=89) | -0.24 [-0.42 to -0.06] | 0.01 | | |
| **Education** | | | | |
| ≤10 years (n=50) | Ref | | | |
| 11-12 years (n=52) | -0.08 [-0.32 to 0.16] | 0.54 | | |
| ≥13 years (n=88) | -0.03 [-0.25 to 0.19] | 0.78 | | |
| **Activity problems** | | | | |
| No (n=57) | Ref. | | | |
| Yes (n=134) | -0.01 [-0.21 to 0.20] | 0.96 | | |

T2=12-week follow-up

[a] Multiple regression adjusted for age, gender, education, perceived activity problems, center, and baseline ADL motor ability.

[b] A change of ≥0.3 logits in ADL motor ability indicates a clinically relevant change.

Marc Sampedro Pilegaard (f. 1984)

'If you fall behind, run faster. Never give up, never surrender, and rise up against the odds.'

Jesse Jackson (Civil rights leader)

This quote describes the mentality I have as a person, which has been a valuable asset during the process of conducting this PhD project.

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