


# BMJ Open Blended intervention based on acceptance and commitment therapy for informal caregivers of people with dementia (ACT-IC): protocol of a mixed-methods feasibility study

Golnaz L Atefi , Rosalia J M van Knippenberg, Sara Laureen Bartels, Frans R J Verhey, Marjolein E de Vugt

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Department of Psychiatry & Neuropsychology, Alzheimer Centre Limburg, Maastricht University, Maastricht, The Netherlands

## Correspondence to

Golnaz L Atefi;  
[g.atefi@maastrichtuniversity.nl](mailto:g.atefi@maastrichtuniversity.nl)

## ABSTRACT

**Introduction** Numerous caregiver support programmes have shown promise in promoting the mental health of informal caregivers of people with dementia (PwD). However, there is still a lack of evidence-based interventions tailored to the specific needs of this population. This mixed-methods study aims to evaluate the feasibility, acceptability and preliminary efficacy of a blended intervention based on acceptance and commitment therapy (ACT) for informal caregivers of PwD, leading to a better understanding of intervention refinements for future controlled trials.

**Methods and analysis** This study includes an uncontrolled pre–post intervention pilot study. A total of 30 informal caregivers of PwD will be recruited through memory clinics and social media platforms in the Netherlands. The ACT for informal caregiver (ACT-IC) intervention will be delivered over a 9-week period and consists of a collaborative goal-setting session, nine online ACT modules, nine telephone-based motivational coaching sessions and 6 monthly booster sessions following the main intervention period. Feasibility and acceptability will be assessed using attrition rate, adherence to and engagement with the intervention, proportion of missing data and semistructured interviews. Preliminary efficacy will be assessed with retrospective measures of depression, anxiety, stress, sense of competence, burden and self-efficacy at baseline, postintervention, at 3-month and 6-month follow-ups.

**Ethics and dissemination** The Medical Ethical Committee from the Maastricht academic hospital and Maastricht University approved the study. The findings of this study will be shared with healthcare professionals, researchers and public audience through various channels, including scientific publications, conference presentations, online forums and community outreach programmes.

**Trial registration number** NCT05064969.

## INTRODUCTION

Dementia is a neurodegenerative condition that generally affects older adults and leads to cognitive and functional impairment and

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This feasibility study is designed to meet the demand for scalable and personalised interventions, expand the evidence base, and inform future large-scale intervention refinement and controlled trials.
- ⇒ A mixed-method approach may offer a better understanding of reasons for drop-outs, as well as barriers and facilitators that informal caregivers experience over the course of the intervention.
- ⇒ The social interaction (telephone-based motivational coaching) might improve the feasibility and acceptability of the online acceptance and commitment therapy intervention.
- ⇒ Since participation in the study is voluntary, individuals who choose to participate may differ from non-volunteers (eg, high education and familiarity with technology). Therefore, the findings from the sample may not be fully representative of the target population.
- ⇒ This uncontrolled pre–post intervention mixed methods feasibility study includes quantitative measures in one group of informal caregivers and is therefore limited in examining the effectiveness of the intervention.

dependency. The majority of people with dementia (PwD) live at home and receive a variety of unpaid support from their informal caregivers, defined as family members, close relatives, friends or neighbours.<sup>1</sup> Informal caregivers play a substantial role in dementia care by contributing to a better quality of life for PwD and preventing their institutionalisation.<sup>2</sup>

However, an increased emotional engagement and time commitment might lead to chronic stress and anxiety disorders in caregivers and put their physical and mental health at risk.<sup>1</sup> Among numerous psychological interventions that have been developed

and shown to improve general well-being, acceptance and commitment therapy (ACT) might be specifically noteworthy.<sup>3</sup> ACT is a transdiagnostic and evidence-based approach that focuses on shared risk factors of a broad range of mental health disorders rather than narrow support for specific psychological issues. According to the theory underlying ACT, accepting unchangeable circumstances and acknowledging demanding situations, especially when they are beyond control, may enable an adaptable mindset and boost psychological flexibility.<sup>4,5</sup>

Specifically, six main processes are involved in achieving treatment goals in the ACT model, including (1) acceptance: facing unwanted thoughts and feelings without attempting to change them; (2) cognitive diffusion: providing distance between oneself and own critical thoughts; (3) being in the present moment: non-judgemental and continuous interaction with environmental occurrences; (4) self as context: adopting a sense of self that is not involved in thoughts and feelings but is open to experience them, (5) values: realising most important areas in life and choosing life directions based on them and (6) committed action: step-by-step process of acting towards values.<sup>6</sup> By discouraging emotional suppression and fostering acceptance of unwanted thoughts (rather than controlling them), ACT might, therefore, facilitate more adaptive coping strategies in informal caregivers to better stay in contact with the present moment.<sup>7</sup> ACT interventions in various modalities (eg, face to face or online) tend to be generally feasible and acceptable for informal caregivers.<sup>8</sup> However, online ACT learning and training might provide larger accessibility to support and facilitate a cost-effective approach in promoting mental health and eventual symptom reduction in this population.<sup>9</sup>

High-quality ACT trials with longer-term follow-up assessments (ie, over 3 months) for informal caregivers of adult (rather than paediatric) patients are still lacking.<sup>8,10</sup> Particularly for informal caregivers of PwD that generally experience higher rates of depression,<sup>1,11</sup> embedding qualitative components and more personal retention approaches (eg, telephone calls) might enhance intervention adherence in online ACT studies.<sup>12</sup> Specifically, collaborative goal setting might offer a promising approach for personalisation, increased intervention compliance and user satisfaction in informal caregivers.<sup>13</sup> Identifying stepwise and measurable goals in collaboration with a motivational coach might support informal caregivers in bringing their learnt skills into practice and taking action towards their values.<sup>14</sup>

This study is the first study to use a mixed-methods approach to evaluate the feasibility, acceptability and preliminary efficacy of a blended online ACT intervention embedded with collaborative goal setting and motivational coaching for informal caregivers of PwD. The key feasibility and acceptability outcomes (eg, user satisfaction, perceived experience) will be informed using an embedded qualitative process evaluation via semistructured interviews. Potential change in caregiver-related

and ACT-related outcomes from preintervention to postintervention and 3-month and 6-month follow-up assessments will be evaluated quantitatively to inform preliminary efficacy.

## METHODS AND ANALYSIS

This protocol will be reported according to guidelines presented in the defining Standard Protocol Items: Recommendations for Interventional Trials.<sup>15</sup>

### Study design

This mixed-methods study includes an uncontrolled pre-post intervention pilot study with a baseline assessment, nine online self-help ACT modules, 9-weekly telephone-based coaching sessions, a postintervention assessment, 6-monthly booster sessions and two postintervention follow-up assessments after three and 6 months. This study is designed to investigate the (1) feasibility and acceptability (primary outcome) and (2) preliminary efficacy (secondary outcome). Quantitative and qualitative process evaluation of recruitment procedure, retention, adherence, participants' perceived experience, user satisfaction and engagement will be used to determine the feasibility and acceptability of the intervention. The preliminary efficacy of the ACT for informal caregiver (ACT-IC) intervention is defined as the extent to which the intervention will potentially improve ACT outcomes and psychological outcomes in informal caregivers under the intervention condition rather than the 'real world' (ie, effectiveness).<sup>16</sup> Preliminary efficacy will be assessed quantitatively using retrospective questionnaires, with data being collected at four assessment points, including pre-post intervention as well as 3-month and 6-month follow-ups. The participants' flow can be seen in figure 1.

### Setting

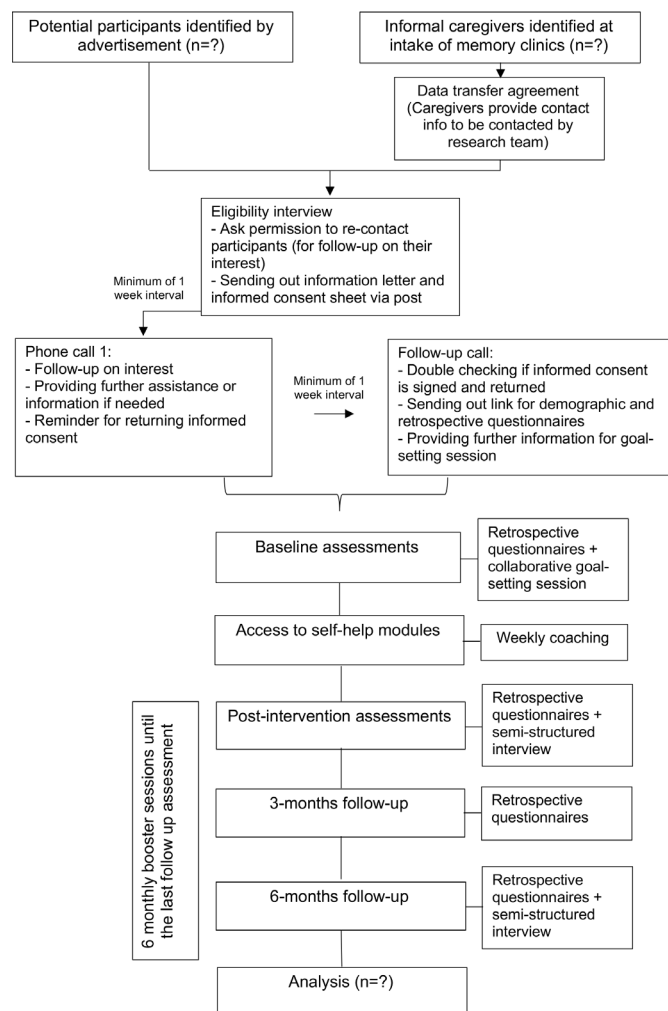
Due to the online nature of the intervention, participants will use their own computers/tablets, and no in-person meetings will take place. Furthermore, participants will receive online guidance from the motivational coach via email, video or phone calls.

### Participants

Potential participants are adult informal caregivers of PwD with no restriction in terms of sex, educational level or cultural background.

### Inclusion criteria

- ▶ Being 18 years of age or older.
- ▶ Self-identified as a primary informal caregiver of a person diagnosed with dementia.
- ▶ Taking care of the care recipient at least once a week for a period of at least 3 months.
- ▶ Access to the internet and tablet/computer in the household.
- ▶ Obtained written informed consent.



**Figure 1** Participants flow in the ACT-IC trial. ACT-IC, acceptance and commitment therapy for informal caregiver.

### Exclusion criteria

- Indicating the presence of a cognitive disorder in the clinical record as self-reported by individuals.
- Receiving psychotherapy or psychopharmacological treatment within the last 3 months (based on self-report)

### Patient and public involvement

None.

### Recruitment and screening

Individuals will be recruited using two approaches: (1) healthcare: clinicians (eg, psychiatrist or psychologist) will approach informal caregivers of PwD during the intake at the memory clinic of the Academic Hospital Maastricht. Individuals who are interested in receiving information about the ACT-IC trial can sign a 'data transfer agreement' to be contacted by the research team. (2) Self-referral: advertisements in the form of digital flyers will be posted on relevant social media sites (eg, Dutch Alzheimer Association), mental health institutions and websites of patient support organisations. Interested individuals can then get more information about the study by calling or emailing

the research team. Regardless of the way of recruitment, a 10 min eligibility interview will be conducted by a trained research assistant for all interested individuals. Further information regarding the background of the study, procedure, voluntary nature of the study, risks and benefits of being in the study, data handling, user privacy, contact information of the research team, complaints procedure and contact detail of an independent expert will be provided in an information letter via post. When the research team receives signed informed consent (in paper format), the study will officially start, and a link to the online questionnaire booklet will be sent to the participant's email address. Possible technical questions and further information about scheduling a video or phone call appointment for the goal-setting session will be addressed during the follow-up telephone calls.

Reasons for non-participation will be collected and used to inform the acceptability of the intervention and recruitment barriers. However, providing reasons for non-participation is optional, and informal caregivers are not required to report why they do not wish to participate.

### Intervention

The ACT-IC blended intervention has four main components, including (1) collaborative goal setting, (2) nine internet-delivered ACT-based modules, (3) 9 weekly motivational coaching and (4) 6-monthly (postintervention) booster sessions guided by a motivational coach. Each component is elaborated on below.

#### Collaborative goal setting

During the baseline assessment, following the concept of collaborative goal setting,<sup>17</sup> each participant will individually discuss their personal values with an experienced and trained motivational coach based at Maastricht University. Following the adapted version of the valued-living questionnaire for dementia caregiving,<sup>18–20</sup> a preset list of values as examples and sources of inspiration will be offered to each participant (table 1).

After deciding on a specific value (eg, mobility), the participant and motivational coach will translate the target value into a specific goal (eg, increasing physical activity). The weight of each goal will be defined by the level of importance and difficulty (1=a little important/difficult, 2=moderately important/difficult, 3=very important/difficult). Following the SMART framework and Goal Attainment Scaling (GAS), each described goal should be Specific in terms of targeting a particular behaviour (eg, walking), Measurable (eg, three times a week), Attainable (eg, for 15 min), Realistic and Timely (eg, in a period of 1 month).<sup>21</sup>

The SMART goal attainment will be mapped in a prespecified ordinal scale, and the number of attainment levels will be the same for all goals ranging from -3 to 2. In the above-mentioned example, the potential SMART goal will be set at level '0' as the 'expected' level that can be achieved (eg, 15 min of daily walks three times a week). The other levels will be defined by a possible change in





**Table 1** An overview of informal caregivers' potential personal values

Self-development	Learning, training or improving skills, finally start a long-awaited activity, raising knowledge about a particular concept, explore something that has been a long-time interest, educating yourself, art, creative expression and aesthetics
Physical self-care	Exercise, physical activity, increasing inside or outside mobility individually or in a group, body movement or any type of sports such as yoga or walking
Social life	Spending time with friends, communities, neighbours, social activities, talking to people with shared interests, making friends or meeting new people, group actions
Recreation	Leisure activity, fun, any kind of hobby, short trips in nature, relaxation, movies, music, photographing, reading novels and stories, cooking or any other activity that brings joy and emotional satisfaction
Caregiving	Improving balance of caregiving responsibilities, care-related time-management and self-management, spending quality time with the care recipient
Health	Self-care, diet, skin care, sleep and/or any kind of medical support to achieve a greater sense of health and well-being or reduce pain, starting a new healthy habit/routine and behaviour, increasing mental health, follow-up or check-up on previous decease, visiting a chiropractor, optometrist, etc
Work	Starting or improving skills that help with employment, retirement or any type of job or profession-related responsibilities
Spirituality	Pray, worship, religious studies or spiritual activity that may be associated with peace of mind
Family relation	Spending quality time with other family members, children, siblings, cousins, spouse, partner, couples or any family-related activity
Citizenship	Moving forward with legal processes of selling/buying properties, registering/cancelling selective services

goal attainment. Any progress from the 'expected level' will be scored '+1' as the 'better than expected' level or '+2' as the 'much better than expected' level. Deterioration in goal attainment will be scored '-3' as the 'much less than expected level' and '-1' as the 'less than expected' level. The '-2' score attributes to the 'current' level at preintervention and addresses 'no change' from the goal-setting day. Setting an in-between '-2' score as the 'current' level is recommended in previous research in order to prevent floor effects and capture deterioration from the 'current' individuals' state.<sup>21</sup> Each level will be prespecified before the intervention as an 'action list' and will be used as a weekly evaluation of goal attainment.

### ACT modules

Nine existing module packages are available online, allowing users to access self-help ACT material with a specific focus on enhancing psychological flexibility.<sup>22</sup> Modules will be released on a weekly basis, and each module consists of a brief introductory text, a short video, content-oriented assignments and a brief feedback questionnaire.

Participants can access the intervention online via their own tablets or computers and complete the assignments at their own convenient time. In order to provide time flexibility, participants will have 12 weeks in total to complete all nine modules. An overview of the modules is shown in [table 2](#).

### Weekly motivational coaching

The same motivational coach as during the collaborative goal setting will be involved during the entire study to motivate each participant to stay engaged with the intervention. Providing guidance in self-help (online) interventions have been suggested to reduce the rate of

drop-out and improve intervention outcomes.<sup>23 24</sup> This study provides a 'minimal contact' self-help intervention in which the motivational coach is involved in offering (technical) support during the intervention without the intention of providing therapy.<sup>25</sup> During the weekly coaching sessions via video or phone call, the coach will ask how participants would rate their level of goal attainment (ie, self-report) and why. Reflections of caregivers will provide a further understanding of how internal (thoughts and feelings) and external (ie, environmental) factors play a role as facilitators and barriers in caregivers' motivation. Finally, the coach will encourage participants to stay engaged with their values, remind them to apply ACT skills in everyday life and motivate them to continue pursuing their SMART goals.

### Monthly booster sessions

After the nine modules blended with motivational coaching are completed, the same motivational coach will provide a total of six booster sessions to each participant via video or phone call (one session per month) for a period of 6 months and until the last follow-up assessment. Booster sessions are recommended as a promising strategy for the maintenance of change in caregivers' interventions.<sup>26</sup> Monthly booster sessions will follow the same format and length as weekly coaching. Participants will have continuous access to the ACT modules during these 6 months.

### Assessment

The extent to which the intervention was implemented as intended (ie, intervention integrity) will be evaluated independently by Clinical Trial Centre Maastricht. Several types of monitoring visits for the purpose of quality/control will be conducted at the beginning of the study

**Table 2** An overview of the ACT modules

Title and description ACT strategies	
Module 1: Introduction	A brief introduction to ACT
Module 2: Identifying how informal caregivers currently deal with unpleasant thoughts and feelings	Introduction: Creative hopelessness Stop fighting unpleasant thoughts and feelings
Module 3: Acknowledging the potential struggles of caregivers with their negative emotions	Core 1: Acceptance Making room for accepting unpleasant feelings
Module 4: Individuals might tend to take their thoughts seriously and fused with them, as if their thoughts are truths	Core 2: Diffusion Distance yourself from difficult thoughts
Module 5: Individuals might have a tendency to define their self-image based on who they are but also who they should or would like to be and this attitude might be stressful	Core 3: Self as context Creating room for individuals to be themselves and be flexible with their self-image
Module 6: Focusing too much on the past ('if only I had...') or the future ('what if...') might not always be helpful	Core 4: Here and now Paying sufficient attention to the present moment which is the only moment when we can actually live, act and experience
Module 7: Acknowledging things that really matter in one's own life	Core 5: Values Actively asking/practicing whether values are sufficiently present in individuals' life
Module 8: Defining concrete and feasible actions towards values facilitates individuals to live a more meaningful life	Core 6: Committed action Actively investing in values and translating them into value-based actions
Module 9: Resilience allows you to deal with your problems in a more flexible way and to fill your life in a way that is valuable to you	Conclusion: Psychological flexibility practising six core skills together to gain psychological flexibility and personal resilience
ACT, acceptance and commitment therapy.	

(ie, Site Initiation Visit); during the intervention (ie, Interim Monitoring Visits); when all data are collected, and subjects have completed the study (Close-Out Visit). After completing the last module, participants will be notified that the intervention study is finished, coaching will be discontinued, and the modules will not be accessible. An incentive voucher with a value of €25 will be sent to participants who complete the study.

### Demographics

Demographics will be assessed at baseline only. Data on sex, level of education, relationship with PwD (eg, sibling, spouse), living situation (eg, whether informal caregiver and PwD live together or independently), type of dementia (eg, Alzheimer's diseases), duration of the disease (years since diagnosis) and average time spent on caregiving (ie, hours per week) will be collected after obtaining informed consent.

Outcome measures can be grouped into four main categories: (1) feasibility and acceptability outcomes; (2) general psychological outcomes; (3) ACT-related outcomes and (4) goal-attainment outcomes.

### Goal attainment

The GAS method will be used as a measure of treatment-induced change. GAS enables comparisons of an individual's relative success in achieving personal goals that are determined preintervention.<sup>27</sup> This factor will be measured during 9-weekly coaching and 6-monthly booster sessions in a prespecified ordinal scale with the

number of attainment levels ranging from -3 (much less than expected) to 2 (much better than expected), with 0 indicating that the goal is attained and -1 as the current level at preintervention.

### Semistructured interview based on the Program Participation Questionnaire

An adjusted version of the Program Participation Questionnaire (PPQ) will be used to examine the extent to which the intervention is acceptable or suitable for the target population.<sup>25</sup> In a semistructured interview, participants will rate and reflect on 26 questions focusing on the intervention components (ie, SMART goal setting, online modules and motivational coaching). The aspects to be assessed include the feasibility, usability, acceptability, applicability of the intervention in everyday life, the perceived experience of content quality and quantity, the adaptation to caregiving role and suggestions for improvement. Each item is graded on a scale from one (strongly disagree) to seven (strongly agree) (see online supplemental appendix 1). The feasibility and perceived experience of the coach will also be evaluated using a brief PPQ semistructured interview based on a previous study.<sup>14</sup> The six-item questionnaire will be used to evaluate the intervention's usability and relevance for the coaches, with four multiple choice answers, scored on a 7-point scale (1=strongly disagree to 7=strongly agree) and four open-ended items on the general perceived experience, programme's positive and negative aspects as



**Table 3** An overview of the feasibility and acceptability outcomes

Focus area	Evaluation
Recruitment process	<ul style="list-style-type: none"> <li>▶ No of referred informal caregivers from memory clinic and social media</li> <li>▶ No of eligible participants willing/not willing to participate and reasons for declined participation (if provided)</li> <li>▶ Amount of time spent on recruiting at least 30 participants</li> <li>▶ The no of drop-outs during the baseline assessment (after signing informed consent and before starting the intervention), and reasons for drop-out (if provided)</li> </ul>
Data collection and procedure	<ul style="list-style-type: none"> <li>▶ Content comprehension will be assessed through an online self-report questionnaire after completing each ACT module</li> <li>▶ Engagement in weekly coaching sessions</li> <li>▶ Reasons for intervention drop-out after starting the intervention (if provided)</li> </ul>
Implementation	<ul style="list-style-type: none"> <li>▶ Postintervention semistructured interviews will be conducted to better understand participants' and coach's experience (feedback will reflect on satisfaction with the implementation and with the overall intervention approach)</li> </ul>
ACT, acceptance and commitment therapy.	

well as suggestion for improvements (see online supplemental appendix 2).

The recruitment procedure, data collection and implementation will be tracked to provide a further understanding of intervention feasibility.<sup>28 29</sup> Furthermore, the acceptability of each module will be evaluated online and on module completion. The feedback questionnaire will be appeared on module completion and involves three items, including 'I found this week's module useful', 'I have experienced the content of the modules as stressful' and 'I can apply the content of this week's module in my daily life'. Scores range from 1 (totally agree) to 7 (totally disagree). An overview of feasibility and multiple areas is shown in [table 3](#).

### Measures of preliminary efficacy

This study is designed to measure feasibility (primary outcome) and preliminary efficacy (secondary outcome). All instruments are validated in the Dutch language.

### Depression, anxiety and stress

Emotional states will be assessed by Depression, Anxiety and Stress Scale (DASS-21) self-report questionnaire. DASS-21 is a validated scale and has three sections (seven items per section) that measure depression, anxiety and stress on a 4-point Likert scale (0=the statement did not apply to me at all, 4=the statement applied to me very much or most of the time.<sup>30</sup>

### Sense of competence

Informal caregivers' sense of competence indicates the feeling of being capable of caring for a person with dementia. Short Sense of Competence Questionnaire is a valid and reliable scale and consists of seven items rated on a 5-point scale from 1 ('agree very strongly') to 5 ('disagree very strongly').<sup>31</sup>

### Burden

Caregiver burden will be measured by a one-item perseverance-time questionnaire. This measure is a

good predictor for institutionalisation and will ask: if the informal caregiver's current situation persists, for how long (in months) the informal caregiver thinks they are able to maintain caregiving.<sup>32</sup>

### Self-efficacy

The Caregiver Self-Efficacy Scale (CSES) will be used to assess caregiver self-efficacy. Previous research has shown that CSES is a valid and reliable scale with item scores ranging from 1 (uncertain) to 10 (very certain).<sup>33</sup>

### Process measures

#### Acceptance

Acceptance is defined as the willingness to face challenging situations. This factor will be assessed using the 10-item Acceptance and Action Questionnaire II, which is reported to be valid, reliable and psychometrically consistent. Items are scored on a 7-point Likert scale, in which higher scores indicate higher acceptance.<sup>34</sup>

#### Psychological flexibility and resilience

Changes in psychological flexibility and functional coping with negative thoughts and feelings in informal caregivers will be assessed using the Flexibility Index Test-60. This reliable and valid questionnaire consists of 60 items and is scored on a seven-point Likert scale (0=completely disagree, 6=completely agree). A higher score reflects higher psychological flexibility.<sup>35</sup>

#### Value

The most important area at the current stage of life will be considered as individuals' 'value'. This factor will be assessed by the Valued Living Questionnaire in which individuals rate the level of importance of 12 different areas (eg, family, work) on a 10-point Likert scale (1=the area is not important at all, 10=the area is very important).<sup>20</sup>

#### Committed action

The extent to which individuals have been actively living in accordance with their values will be assessed by

the 16-item Engaged Living Scale. This validated scale consists of 16 items in which individuals should reflect in statements based on a 5-point Likert scale (1=strongly disagree, 5=strongly agree).<sup>36</sup>

### Sample size

Sample sizes of  $n=30$  participants are recommended in previous research to be an appropriate number for sufficient information on feasibility outcomes.<sup>37 38</sup> This number enables the calculation of the key factors relevant to determine feasibility (eg, attrition rates) and provides a reasonable indication of the preliminary efficacy and likely sample size required for a larger controlled trial.<sup>39</sup> Therefore,  $n=30$  informal caregivers of PwD will be recruited for this trial.

Quantitative and qualitative data will be collected at six points in time.

### Planned data analysis

Quantitative (descriptive and inferential statistics) analyses will be conducted. In particular, data will be summarised using mean $\pm$ SD, median $\pm$ IQR, minimum and maximum for continuous and discrete outcomes, whereas the number of events and percentages will be used to summarise categorical data.

The PPQ result will be first analysed quantitatively (eg, mean, range and percentiles). Due to the lack of external criteria to properly define feasibility,<sup>40</sup> in line with previous studies, the conventional strategy of defining the median scores as cut-off scores will determine the overall feasibility, usability and acceptability.<sup>27 41</sup> This method was used in a Delphi research to evaluate intervention feasibility.<sup>42</sup> Mean item scores of 5 (slightly agree) or above will be regarded as positive, while mean item scores below 4 (slightly disagree or lower) will be considered as a need for further improvement. Scores will be elaborated by participants, in which their reflections will be audiorecorded and transcribed verbatim. The qualitative data of PPQ will be analysed using deductive content analysis to identify meaningful data units.<sup>43</sup> Further, the number of log-ins and web features used will be collected and subsequently compared with self-reported data.

Results from retrospective questionnaires will be analysed using intention-to-treat principles via repeated measure multivariate analysis of covariance models accounting for confounders. Missing data in questionnaires will be analysed according to the missing rate and manual of each specific questionnaire. If necessary, adequate imputation techniques will be applied.

The level of goal attainment will be collected during 9-weekly coaching and 6-monthly booster sessions via telephone or video calls. The level of goal attainment will range from  $-3$  (much lower than expected) to  $+2$  (much better than expected), with a score of 0 indicating goals attained and  $-1$  indicating the current level at preintervention. Following previous studies, raw scores will be transformed into T-scores. Mean GAS scores (T-scores)

will be calculated for each measurement time point to determine potential improvement in goal attainment.<sup>27</sup>

### ETHICS AND DISSEMINATION

This study has no risks of injury for the subjects by its nature, and it is approved by the Medical Ethics Committee of the Maastricht University Medical Centre (NL77389.068.21/metc21-029.). The trial will be conducted according to the principles of the Declaration of Helsinki (latest version, see [www.wma.net](http://www.wma.net)) and in accordance with the Medical Research Involving Human Subjects Act (WMO). Results will be disseminated through relevant healthcare and patient communities, peer-reviewed journals and conferences for the wider public.

### Confidentiality and informed consent

Participants' privacy and dignity will be protected, and participant data confidentiality both during and after the study will be ensured. During the eligibility check, individuals will be informed that they will receive an information letter and informed consent sheet, have at least 1 week to consider participation and can return the signed informed consent using the attached self-addressed stamped envelope if they are interested in participating. Potential participants will be asked to give permission for follow-up phone calls. A research assistant and an independent expert will be available for further information before, during and after the intervention.

### Data handling

Retrospective questionnaires and quantitative data will be directly entered into a safe online case record portal (CASTOR), adhering to data privacy rules and Good Clinical Practice regulations.<sup>44</sup> The qualitative data, including semistructured interviews, will be audiorecorded, stored as mp3 files, pseudonymised and transcribed verbatim. Data will be handled in accordance with the EU General Data Protection Regulation and the Dutch Act on Implementation of the General Data Protection Regulation. All data will be stored in the secured servers of the Department of Psychiatry and Neuropsychology of Maastricht University, and three monitoring visits at the beginning, during and at the end of the study will be conducted. The Central Committee for the Protection of Human Subjects in Research will perform monitoring visits at Maastricht University for the purpose of quality control. In accordance with the central committee statement on research involving human subjects publication policy, the results will be disclosed unreservedly.

### DISCUSSION

The blended ACT-IC intervention embedded with motivational coaching will be conducted in response to previous research demonstrating the need for additional ACT trials for informal caregivers of adult patients.<sup>8 10</sup> ACT, by targeting shared needs (eg,



psychological flexibility) among individuals, may show a beneficial impact on a broad range of factors affecting well-being and adaptive coping strategies among informal caregivers of PwD.<sup>12 45</sup> The essential goal of ACT is to address emotional, cognitive and behavioural avoidance and promote psychological flexibility.<sup>5</sup> In this study, the online self-help modules of the ACT-IC intervention target psychological flexibility through exercises and prerecorded videos focused on acceptance, cognitive diffusion, being present, self as context, values and committed action. Furthermore, specific goals will be aligned towards personal values in collaboration with a motivational coach and as guidance for committed actions.<sup>46</sup> Therefore, informal caregivers will have an opportunity to customise the intervention towards their personal values and can plan to meet them. Value-based activities in the context of caregiving can be defined as the extent to which caregivers live in line with their most important values in life.<sup>18</sup> Moving towards values has been highlighted to be positively associated with emotional well-being<sup>19</sup> and negatively associated with distress<sup>47</sup> and can lead informal caregivers to better psychological, social and physical outcomes.<sup>48</sup>

Qualitative assessment of outcomes and the mixed-method design of the current study will provide valuable insights into characteristics and experiences related to drop-out or retention and will provide a better understanding of the intervention acceptability and barriers of psychological flexibility in informal caregivers. Moreover, human contact through motivational coaching will create a powerful retention approach and might facilitate informal caregivers to acknowledge their thoughts and feelings while pursuing their values and goals.<sup>13 33</sup>

Participation in this study is voluntary, and the sample might not be fully representative of the target population. However, a mixed-methods design to assess the acceptability and feasibility of the intervention is of great importance in informing intervention refinements for a future controlled trial. The broader scope of inclusion criteria will facilitate recruiting a diverse and heterogeneous population and increase the generalisability of the findings to informal caregivers of patients with any type or stage of dementia. Moreover, due to the limited number of ACT intervention studies conducted for this target population, the follow-up assessments will provide valuable insight into whether booster sessions for informal caregivers can consolidate the outcomes of the interventions sustainably over time.<sup>26 49</sup> Finally, the results will be informative to design and conduct prospective controlled trials.

## Study status

Recruitment started in May 2022.

**Correction notice** This article has been corrected since it was published. Author names have been corrected.

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**Contributors** GLA, RJMvK, SLB, FRJV and MeDV designed the research. GLA and RJMvK applied for ethical approval. GLA registered the trial and drafted the manuscript. All authors revised and approved the final manuscript.

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**Competing interests** None declared.

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## ORCID iD

Golnaz L Atefi <http://orcid.org/0000-0002-9465-6013>

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Semi-structured interview for each participant (post- intervention):

<b>Participation in the “ACT-IC” intervention</b>								<b>Reflection</b>
<b>1. I enjoyed the collaborative goal-setting with the motivational coach</b>	1	2	3	4	5	6	7	Why/why not? - Possible points for improvement?
<b>2. The action list for my goals helped me to structure a way to change my undesired situations</b>	1	2	3	4	5	6	7	Why/why not? - Possible points for improvement?
<b>3. I think the weekly coaching was a good addition to the program</b>	1	2	3	4	5	6	7	Why/why not? - Possible points for improvement?
<b>4. Weekly talk to the coach motivated me to follow my goals</b>	1	2	3	4	5	6	7	- Possible points for improvement?
<b>5. I found the duration of the coaching sessions (~20 minutes) sufficient</b>	1	2	3	4	5	6	7	- - Shorter or longer?
<b>6. I think one week interval between coaching sessions was enough</b>	1	2	3	4	5	6	7	- Shorter or longer?
<b>7. I made use of:</b>								
<b>7a. Conversations with the coach</b>	1	2	3	4	5	6	7	- Why/why not? - What did/didn't appeal to you in this?
<b>7b. The step-by-step plan toward my goals</b>	1	2	3	4	5	6	7	- Why/why not? - What did/didn't appeal to you in this?
<b>Open reflection</b>								- How did you find the intervention? - Did you struggle with or miss any web features? - Would you delete any certain features? Which/why?
<b>8. I could read the text on the website well</b>	1	2	3	4	5	6	7	- points regarding text size, contrast, amount?
<b>9. I liked the amount of information offered per module</b>	1	2	3	4	5	6	7	- Points regarding length of the video, amount of text in the introduction?

<b>10. I found the content of the modules clear and easy to understand</b>	1	2	3	4	5	6	7	- Easy to understand/follow? - Why/why not?
<b>11. I found the modules useful</b>	1	2	3	4	5	6	7	- Why/why not? - Possible points for improvement?
<b>12. I liked the amount of time I spent on each module</b>	1	2	3	4	5	6	7	- How much time did you spend per module? - What did you spend the most time with? - Would you have preferred to spend more/less time on it?
<b>13. I found one week interval between modules enough</b>	1	2	3	4	5	6	7	- Possible points for improvement?
<b>14. I liked the number of modules (9)</b>	1	2	3	4	5	6	7	- More or less?
<b>15. I made use of:</b>								
<b>15a. The introductory videos</b>	1	2	3	4	5	6	7	- Why/why not? - What did/didn't appeal to you in this regard?
<b>15b. The assignments</b>	1	2	3	4	5	6	7	- Why/why not? - What did/didn't appeal to you in this regard?
<b>Open reflection</b>								- Did you find it complete? - Did you miss any features? Suggestions? - Would you delete certain features? Which?
<b>16. I liked the structure of the modules (action list, step-by-step plan, modules, coaching).</b>	1	2	3	4	5	6	7	Logical structure - Did you follow all the components? Why/why not? - What part(s) of the intervention did you find most helpful or effective and what parts not? - Did you miss any component?
<b>17. I am generally satisfied with what was offered to me during the intervention</b>	1	2	3	4	5	6	7	- Why/why not? - Possible points for improvement?



<b>18. I have used the information offered during the intervention in my daily life</b>	1	2	3	4	5	6	7	- Why/why not? - What was that about?
<b>19. After taking the course, it is easier for me to find the balance between my personal needs and my caregiving responsibilities</b>	1	2	3	4	5	6	7	- Why/why not? - What was that about?
<b>20. The course helped me to critically evaluate my situation</b>	1	2	3	4	5	6	7	- Why/why not? - Possible points for improvement?
<b>21. After following this program I know how to deal with unwanted situations more easily in the future</b>	1	2	3	4	5	6	7	- Why/why not? - Possible points for improvement?
<b>22. I would recommend the program to other carers of people with dementia</b>	1	2	3	4	5	6	7	-Why/why not? - Which aspects in particular?
<b>23. I experienced privacy issues:</b>								
<b>23a. In general</b>	1	2	3	4	5	6	7	-What did you (dis)like? - What was that about?
<b>23b. During communication with my coach</b>	1	2	3	4	5	6	7	-What did you (dis)like? - What was that about?
<b>24. Open reflection</b> - Is there anything else you would like to say about using the program or your satisfaction with the program?								

Semi-structured interview for the coach (post-intervention):

You started as the motivational coach during the ACT-IC intervention. Please tell us about your experience and your role.  
This questionnaire consists of both closed and open questions. You can always provide an explanation for your response;

<b>Motivational coach of the "ACT-IC" intervention</b>	1= Strongly agree 7= Strongly disagree	<b>Reflection</b>
<b>1. As a coach, I found the intervention useful</b>	1 2 3 4 5 6 7	- Why/why not? - Possible points for improvement?
<b>2. I could integrate the course into my work</b>	1 2 3 4 5 6 7	- Why/why not? - What did/didn't appeal to you in this?
<b>3. I think the course had added value for informal caregivers</b>	1 2 3 4 5 6 7	- Possible points for improvement?
<b>4. I think the course had added value for me as the coach</b>	1 2 3 4 5 6 7	- Why/why not?
<b>5. I was able to support the participants according to protocol and as planned</b>	1 2 3 4 5 6 7	- Points of improvement?
<b>5. I found the use of coaching beneficial and it was clearly visible within my work with the informal caregivers</b>	1 2 3 4 5 6 7	- Points of improvement?
		Did you find it complete? - Did you struggle or miss any features? Suggestions? - Would you delete any certain features? Which one?
<b>6. Open reflection</b>		
- Is there anything else you would like to say about the use of this intervention or your satisfaction with the program?		

Semi-structured interview for each participant (post- intervention):

<b>Participation in the “ACT-IC” intervention</b>								<b>Reflection</b>
<b>1. I enjoyed the collaborative goal-setting with the motivational coach</b>	1	2	3	4	5	6	7	Why/why not? - Possible points for improvement?
<b>2. The action list for my goals helped me to structure a way to change my undesired situations</b>	1	2	3	4	5	6	7	Why/why not? - Possible points for improvement?
<b>3. I think the weekly coaching was a good addition to the program</b>	1	2	3	4	5	6	7	Why/why not? - Possible points for improvement?
<b>4. Weekly talk to the coach motivated me to follow my goals</b>	1	2	3	4	5	6	7	- Possible points for improvement?
<b>5. I found the duration of the coaching sessions (~20 minutes) sufficient</b>	1	2	3	4	5	6	7	- - Shorter or longer?
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<b>7b. The step-by-step plan toward my goals</b>	1	2	3	4	5	6	7	- Why/why not? - What did/didn't appeal to you in this?
<b>Open reflection</b>								- How did you find the intervention? - Did you struggle with or miss any web features? - Would you delete any certain features? Which/why?
<b>8. I could read the text on the website well</b>	1	2	3	4	5	6	7	- points regarding text size, contrast, amount?
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<b>6. Open reflection</b>		
- Is there anything else you would like to say about the use of this intervention or your satisfaction with the program?		