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

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ABSTRACT

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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

- \Rightarrow This feasibility study is designed to meet the demand for scalable and personalised interventions, expand the evidence base, and inform future largescale intervention refinement and controlled trials.
- \Rightarrow 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.
- \Rightarrow The social interaction (telephone-based motivational coaching) might improve the feasibility and acceptability of the online acceptance and commitment therapy intervention.
- \Rightarrow 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.
- \Rightarrow 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.

data mining, AI training, and similar dependency. The majority of people with technolog 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.¹ Informal caregivers play a substantial role 8 in dementia care by contributing to a better quality of life for PwD and preventing their institutionalisation.²

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.¹ Among numerous psychological interventions that have been developed

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and shown to improve general well-being, acceptance and commitment therapy (ACT) might be specifically noteworthy.³ 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.⁴⁵

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: nonjudgemental 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.⁶ 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.⁷ ACT interventions in various modalities (eg, face to face or online) tend to be generally feasible and acceptable for informal caregivers.⁸ 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.⁹

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.⁸¹⁰ Particularly for informal caregivers of PwD that generally experience higher rates of depression,^{1 11} embedding qualitative components and more personal retention approaches (eg, telephone calls) might enhance intervention adherence in online ACT studies.¹² Specifically, collaborative goal setting might offer a promising approach for personalisation, increased intervention compliance and user satisfaction in informal caregivers.¹³ 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.¹⁴

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

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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

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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 τ paper format), the study will officially start, and a link of to the online questionnaire booklet will be sent to the participant's email address. Possible technical questions ŝ and further information about scheduling a video or 8 phone call appointment for the goal-setting session will be addressed during the follow-up telephone calls.

rigl Reasons for non-participation will be collected and used to inform the acceptability of the intervention and including recruitment barriers. However, providing reasons for nonparticipation 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

text and da During the baseline assessment, following the concept of collaborative goal setting,¹⁷ each participant will individuĩ ally 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,¹⁸⁻²⁰ a preset list of values as examples and sources of inspiration will be offered to each participant (table 1).

ğ 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). <u>0</u> 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 õ 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).²¹

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

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Table I An overv	iew 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
Citizenshin	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.²¹ 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.²² 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.^{23 24} This re 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.²⁵ 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 . ک 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

training, and After the nine modules blended with motivational coaching are completed, the same motivational coach S 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.²⁶ 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

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 \notin 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 treatmentinduced change. GAS enables comparisons of an individual's relative success in achieving personal goals that are determined preintervention.²⁷ 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 Ques-⊳ tionnaire (PPQ) will be used to examine the extent to which the intervention is acceptable or suitable for the target population.²⁵ In a semistructured interview, participants will rate and reflect on 26 questions focusing on ല 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 $\overline{\mathbf{g}}$ 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.¹⁴ 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

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Table 3 An overview of the feasibility and acceptability outcomes			
Focus area	Evaluation		
Recruitment process	 No of referred informal caregivers from memory clinic and social media No of eligible participants willing/not willing to participate and reasons for declined participation (if provided) Amount of time spent on recruiting at least 30 participants 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) 		
Data collection and procedure	 Content comprehension will be assessed through an online self-report questionnaire after completing each ACT module Engagement in weekly coaching sessions Reasons for intervention drop-out after starting the intervention (if provided) 		
Implementation	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)		
ACT accortance and commitment	thorapy		

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.^{28 29} 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.³⁰

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').³¹

Burden

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

Protected by copyright, including 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 for uses related to text and able to maintain caregiving.³²

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).³³

Process measures

Acceptance

Cal 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.³⁴

Psychological flexibility and resilience

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

The most important area at the current stage of life will be considered as individuals' 'value'. This factor will a ssessed by the Valued Living Original viduals 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.²⁰

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).³⁶

Sample size

Sample sizes of n=30 participants are recommended in previous research to be an appropriate number for sufficient information on feasibility outcomes.^{37 38} 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.³⁹ 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±SD, median±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,⁴⁰ 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.^{27 41} This method was used in a Delphi research to evaluate intervention feasibility.⁴² 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.43 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.²⁷

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 otected version, see www.wma.net) and in accordance with the Medical Research Involving Human Subjects Act (WMO). Results will be disseminated through relevant healthcare ş and patient communities, peer-reviewed journals and copyright, 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 use 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 đ before, during and after the intervention. text

Data handling

and data 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.⁴⁴ The qualitative data, including semistructured interviews, will be audiorecorded, stored g 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.⁸¹⁰ 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.^{12 45} The essential goal of ACT is to address emotional, cognitive and behavioural avoidance and promote psychological flexibility.⁵ 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.⁴⁶ 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.¹⁸ Moving towards values has been highlighted to be positively associated with emotional well-being¹⁹ and negatively associated with distress⁴⁷ and can lead informal caregivers to better psychological, social and physical outcomes.⁴⁸

Qualitative assessment of outcomes and the mixedmethod design of the current study will provide valuable insights into characteristics and experiences related to drop-out or retention and will provide a better undressing 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.^{13 33}

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.^{26 49} 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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