

A blended intervention based on Acceptance and Commitment Therapy (ACT) for Informal Caregivers of People with Dementia- A mixed method approach to evaluate feasibility, acceptability and preliminary effectiveness

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50964

Source

ToetsingOnline

Brief title

ACT-IC Study: ACT for informal caregivers of people with dementia

Condition

- Other condition

Synonym

Acceptance and Commitment Therapy for Caregivers of people with Dementia

Health condition

No specific condition of the informal Caregivers of people with Dementia will be studied.

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Funded by Marie Skłodowska-Curie Actions Innovative Training Network (ITN) action;H2020-MSCA

Intervention

Keyword: - Acceptance and Commitment Therapy, - Feasibility, - Informal caregivers, - Internet based intervention

Outcome measures

Primary outcome

Primary outcome measures include:

- Depression, anxiety, and stress (DASS-21)
- Short Sense of Competence Questionnaire (SSCQ-7)
- Burden (The perseverance-time single-item)
- The Caregiver Self-Efficacy Scale (CSES-9)

Secondary outcome

Process measures include:

- Value: Valued Living Questionnaire (VLQ)
- Psychological flexibility: Acceptance and Action Questionnaire II (AAQ-II)
- Resilience: Flexibility Index Test (FIT-60)
- Committed action: Engaged Living Scale (ELS)
- Goal-attainment scaling will be assessed qualitatively

Study description

Background summary

Informal caregivers of people with dementia (PwD) invest time, emotion, and effort in their caregiving responsibilities. Due to various care demands, informal caregivers may experience substantial negative mental health effects such as burden, stress, depression, and anxiety. Therefore, they are holding a unique position of both providing and needing support.

Acceptance and commitment therapy (ACT) is a transdiagnostic and evidence-based approach that empowers individuals to change their behavior toward value-based activities. To date, ACT can be applied not only in face-to-face sessions but also via self-guided online programs, which increases the individual time-flexibility and might be particularly suitable for caregivers of PwD.

Moreover, ACT has shown promise in improving individuals* mental health and overall wellbeing. However, only a small number of studies investigated ACT in older caregivers which is usually found in the context of dementia care.

In addition to ACT, setting realistic goals toward value-based activities supports individuals to orient their actions and subsequently their behavior toward a more meaningful and less distressing life. This strategy might support informal caregivers of PwD further to balance the care demands with their individual needs. However, engaging with life values, defining goals, and taking action toward those values might be challenging and yet require further motivation for informal caregivers of PwD.

Therefore, a web-based ACT intervention blended with complementary components including collaborative goal-setting and motivational coaching might enable informal caregivers of PwD to live a more meaningful and less distressing life.

Study objective

The primary objective of this study is to evaluate the feasibility and acceptability of the blended ACT-based intervention among informal caregivers of PwD.

The secondary objectives are to evaluate (i) the preliminary effectiveness of the blended ACT-based intervention on clinical outcomes (e.g. psychological flexibility), and (ii) maintenance of changes after the intervention in short- and long-term follow ups.

Study design

This study includes a single-arm, non-randomised trial with a baseline assessment, a 9-week internet-based intervention period, a post-intervention assessment, and two follow-ups at 3 and 6 months.

Intervention

All eligible and consenting informal caregivers of PwD will be asked to participate in an individual goal-setting session with a motivational coach. Afterward, participants follow the internet-delivered ACT-based modules on a digital platform called *Embloom*. A total of 9 modules (one module per week) can be completed over 9 to 12 weeks. During the intervention, the motivational coach will contact the participants weekly to encourage them to follow their goals and stay engaged with the modules. After the intervention, 6 monthly booster sessions (one session per month) will be provided by the motivational coach to motivate the informal caregivers to continue their value-based activities or revisit the ACT modules, if needed.

Before and after the intervention as well as at 3-and 6-month follow up, participants will be asked to fill out a number of retrospective questionnaires. Furthermore, a semi-structured interview will be conducted to assess the user experience, feasibility, and acceptability of the intervention.

Study burden and risks

Although the risk of participation in this study can be considered minimal/negligible, engaging with technology and internet-based intervention might be confusing or require effort from older informal caregivers. Furthermore, informal caregivers should follow the modules, fill in the exercises, and at the same time stay actively engaged with their SMART goals. Being called weekly by a motivational coach and staying in touch 6 months after the intervention might be associated with a considerable perceived burden. Individuals who choose to participate in the blended ACT intervention will receive the potential benefits associated with the intervention in terms of their clinical, functional, and social functioning to live a more meaningful and less distressing life. Moreover, an incentive voucher with a value of 25€ will be sent to the research participants who complete the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Adult informal caregivers (at least 18 years old)
- Access to the internet and having a tablet or computer
- Self-identified primary informal caregiver of a person diagnosed with dementia
- Taking care of the care recipient for at least once a week for a period of at least three months
- Obtained informed consent

Exclusion criteria

- Caregivers who report having a cognitive disorder in their clinical record will be excluded (based on self-report).
- Caregivers who receive psychotherapy or psychopharmacological treatment within the last 3 months will be excluded (based on self-report).
- *General (psychological) support from case managers will not count as professional psychological support, and therefore, informal caregivers who receive support from the case managers will also be included.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	12-05-2022
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO	
Date:	20-10-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT05064969
CCMO	NL77389.068.21