STUDY PROTOCOL

Compass for Care: A Digital Self-Care and Well-Being Program for Caregivers of Individuals Living with Alzheimer's Disease and Related Dementias

ClinicalTrials.gov Identifier:
NCT06249139

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1. Background and Rationale

Family caregivers of individuals living with Alzheimer's disease and related dementias (ADRD) experience substantial emotional, physical, and psychological burden. Caregiving responsibilities are frequently associated with increased stress, depressive symptoms, reduced well-being, and diminished quality of life. Digital interventions have the potential to provide scalable, accessible support to caregivers who may have limited time or access to in-person services.

Compass for Care was developed to promote caregiver self-care and well-being through a tailored digital intervention grounded in the Transtheoretical Model of Behavior Change (TTM). The intervention was designed to support caregivers in adopting and maintaining behaviors that contribute to improved well-being and resilience.

2. Study Objectives

Primary Objective

To evaluate the effect of Compass for Care on caregiver burden as measured by the Zarit Burden Interview (ZBI).

Secondary Objectives

To evaluate the effect of Compass for Care on:

• Depressive symptoms
• Resilience
• Well-being
• Perceived stress
• Perceived change
• Overall thriving

Exploratory Objectives

To examine whether intervention effects vary according to participant characteristics and intervention engagement.

3. Study Design

This study was a randomized controlled trial with two parallel study arms:

1. Compass for Care Intervention
2. Attention Control Condition

Participants were randomized in a 1:1 ratio.

Assessments were conducted at:

• Baseline
• 3 months
• 6 months
• 9 months

4. Participants

Eligibility Criteria

Participants were eligible if they:

• Were age 18 years or older
• Provided unpaid care for an individual living with Alzheimer's disease or a related dementia
• Had access to the internet and either email or text messaging
• Were able to complete study procedures in English

Individuals unable to provide informed consent or complete study procedures were excluded.

5. Recruitment and Enrollment

Participants were recruited nationally through caregiver organizations, community outreach efforts, online recruitment strategies, and partner organizations serving ADRD caregivers.

A total of 305 caregivers were enrolled and randomized:

• Compass for Care: n=152
• Attention Control: n=153

6. Intervention Conditions

Compass for Care

Compass for Care was a 12-week digital intervention delivered through an online platform combined with tailored text and/or email messaging.

Content focused on five behavioral domains:

• Getting the information you need
• Figuring out your strengths and limits
• Searching for and accepting outside help
• Taking care of yourself
• Getting emotional support

The intervention included personalized assessments, tailored feedback, interactive activities, goal-setting tools, progress tracking, and ongoing messaging designed to support behavior change and caregiver well-being.

Attention Control Condition

The attention control condition was developed specifically for this study and provided a structured 12-week curriculum focused on caregiver safety topics, including financial, home, and online safety. Participants also received regular text and/or email reminders and educational content to promote engagement throughout the study period.

7. Outcome Measures

Primary Outcome

• Zarit Burden Interview (ZBI)

Secondary Outcomes

• Patient Health Questionnaire-8 (PHQ-8)
• Resilience Evaluation Measure-3 (REM-3)
• World Health Organization Well-Being Index (WHO-5)
• Perceived Stress Scale (PSS)
• Perceived Change Index (PCI)
• Cantril Overall Thriving

8. Data Collection Procedures

Participants completed online assessments at baseline, 3 months, 6 months, and 9 months. Intervention engagement metrics, including logins and activity completion, were collected throughout participation.

9. Statistical Analysis

The primary analysis compared changes over time between study groups using longitudinal mixed-effects modeling.

Continuous outcomes were analyzed using linear mixed-effects models including fixed effects for group, time, and group-by-time interaction, with participant-level random intercepts.

Ordinal outcomes were analyzed using ordinal logistic mixed-effects models.

The binary thriving outcome was analyzed using generalized estimating equations with a logistic link function.

Moderator analyses examined the influence of intervention engagement, demographic characteristics, and caregiving characteristics on study outcomes.

All statistical tests were two-sided with alpha = 0.05.

10. Oversight and Ethical Considerations

The study was reviewed and approved by Pro-Change's Institutional Review Board (IRB). Study progress was monitored by a Data Safety and Monitoring Committee (DSMC). All participants provided informed consent prior to participation.