



# Efficacy of the I-SOCIAL intervention for loneliness in old age: Lessons from a randomized controlled trial

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## ABSTRACT

Loneliness is common among older persons and is associated with adverse health and wellbeing outcomes. We investigated a theory-based intervention that addresses barriers to social contacts and aims at increasing social self-efficacy. Individuals that met pre-assessment criteria of cognitive function, physical health, and loneliness levels were randomly assigned either to the I-SOCIAL intervention that combined both individual and group sessions to address individuals' unique social challenges, or to the control group. Assessment was administered at baseline, after the completion of the intervention, and after a 3-month follow-up period. The intervention group showed significant decline in loneliness level compared to the control group, both after the intervention and after the follow-up period. This innovative combination of analysis of personal barriers, support provided by the counselors, group activities, and individualized suggestions for social activities in the participant's neighborhood, may account for the success of the intervention in decreasing participants' loneliness levels.

## 1. Introduction

Loneliness has long been recognized as a persistent problem among older populations, with reported prevalence ranging from 10% to 45% of older persons depending on their gender, age group, and method of assessing loneliness (Brodsky et al., 2017; Cohen-Mansfield et al., 2009; Niedzwiedz et al., 2016). It generally refers to the person's subjective experience of inadequate quality or level of relationships (Lopata, 1969; Russell et al., 1984; Weiss, 1973). In contrast to loneliness, "social isolation" refers to the objective aspect of limited social interactions. (Chappell and Badger, 1989; de Jong Gierveld et al., 2018; Dykstra, 2009; Weiss, 1973; Wenger et al., 1996).

Multiple factors affect loneliness in older adults. A review of correlates (Cohen-Mansfield et al., 2016) found demographic variables such as female gender, non-married status, older age, and poor income to be related to higher levels of loneliness. Psychological attributes such

as poor mental health, low self-efficacy beliefs, cognitive deficits, as well as social attributes (e.g. quality and quantity of social networks) and medical and functional status, were also associated with loneliness. Furthermore, limited financial resources and insufficient opportunities for social contact were found to be significant predictors of loneliness (Cohen-Mansfield and Parpura-Gill, 2007). Successful social integration is dependent on an appropriate environment and on adequate social skills (de Jong Gierveld et al., 2018).

Creating avenues for social integration for those who have difficulty fulfilling their social needs is of paramount clinical significance for preventing the adverse outcomes of loneliness (Heinrich and Gullone, 2006). Reported negative outcomes of loneliness include poor overall health, higher blood pressure (Luanaigh and Lawlor, 2008), coronary issues (Sorkin et al., 2002), depressed affect, faster cognitive deterioration (Donovan et al., 2017; Golden et al., 2009), as well as Alzheimer's disease (Wilson et al., 2007), poor quality of life (Chalise et al.,

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2010; Paul et al., 2006), and increased mortality rates (Penninx et al., 1997; Seeman, 2000; Shiovitz-Ezra and Ayalon, 2010; Sugisawa et al., 1994).

Intervention studies which aimed to decrease loneliness have been based on either group or individual formats, and they involved different kinds of content, such as psychological help, (e.g. social skills training), recreational activities (such as art or exercise), or practical help (e.g., using hearing aids). Furthermore, although various interventions seem promising, their efficacy was questionable due to flawed research designs (Cohen-Mansfield and Perach, 2015), and they have been unable to provide conclusive evidence (Cattan et al., 2005).

The current study addresses limitations of past studies in several ways. First, the intervention developed for this study, the Increasing SOcial Competence and social Integration of older Adults experiencing Loneliness (I-SOCIAL) intervention, is theory-based. It is grounded in the general framework of a Cognitive-Behavioral theoretical model, conceptualizing behaviors as resulting from the interaction between personal and environmental factors, as well as being based on the Model of Depression and Loneliness (MODEL), which identified specific barriers to social integration among lonely older individuals (Cohen-Mansfield and Parpura-Gill, 2007). Second, the intervention integrates individual and group sessions. Third, we aimed to decrease the methodological flaws by conducting a randomized controlled trial.

## 2. Methods

### 2.1. Participants

We recruited 136 potential participants from many sources, including two local branches of a Health Maintenance Organization (HMO; 36 participants), calling people from a list of local older persons purchased from a commercial vendor (36 participants), local senior centers and university lectures open to the public (19 participants), persons referred from other studies or through other participants of this study (13 participants), responses to posters advertising the study (13 participants), referrals from the municipal social service agency (12 participants), and local residential buildings for older persons (7 participants). A total of 89 persons were randomized (44 = control, 45 = intervention, i.e., receiving the I-SOCIAL intervention); of these 74 participants completed the intervention (35 = control, 39 = intervention), and 63 completed follow-up (28 = control, 35 = intervention). A flow diagram presenting recruitment and exclusions of potential participants is presented in Fig. 1. Participants' demographic characteristics are described in Table 1.

### 2.2. Assessments

**Pre-intervention questionnaire.** *Demographic information* included gender, age, marital status, place of birth, and years of education. *Health* was assessed by number of medical diagnoses. *Subjective health* was rated on a 4-point scale (poor, fair, good, excellent). *Cognitive function* was assessed using the validated Hebrew version of the Mini Mental State Examination (Folstein et al., 1975; Werner et al., 1999). The total score ranges from 0 (severe cognitive impairment) to 30 (normal cognitive functioning).

**Outcome variable.** *Loneliness* was assessed by three measures: (a) The UCLA Loneliness Scale- 8 items (ULS-8; Hays and DiMatteo, 1987). Each item was rated on a 5-point scale from “not at all” (1) to “to a great extent” (5), with a higher score indicating greater loneliness. The rating scale of two items, “I am an outgoing person” and “I can find companionship when I want it” was reversed. Based on experience from another study (Cohen-Mansfield et al., 2015), “I am unhappy being so withdrawn” was replaced with two items: “I feel physically distant from other people” and “I feel emotionally distant from other people”; (b) *Frequency of loneliness* was measured via “How often would you say you feel lonely?” (Mullins et al., 1990) on a 6-point scale from “never”

(1) to “several times an hour” (6); (c) *Severity of loneliness* (Holwerda et al., 2014) was measured via “To what extent do you feel lonely?” measured on a 5-point scale from “not at all” (1) to “to a very large extent” (5). The three measures were highly inter-correlated, with correlations at baseline ranging from  $r = .50$  to  $r = .65$  with sample sizes ranging from 117 to 132,  $p < .001$ . We therefore used the mean of the three measures (after transforming the frequency measure to a 1–5 range to equalize its weight to the other two measures) as the outcome variable for the study.

### 2.3. Procedure

The ethics committee of Tel-Aviv University approved the study as did the Helsinki ethics committee of Meir Medical center. The study was registered at ClinicalTrials.gov (identifier NCT01842984). Inclusion criteria were (1) age 65 and above; (2) feeling lonely based on the questions of degree (moderate level and above) and frequency (several times a week and above) of loneliness on the screening questionnaire, as well as not participating in social activities and expressing at least moderate desire to have additional company; (3) being able to participate based on cognitive function (MMSE > 22); (4) no significant depression as screened by the Geriatric Depression Scale (GDS). We used a cut-off of 10, which indicates moderate depression.

All individuals recruited were interviewed in-person by a research assistant to complete the pre-intervention questionnaire, which included items on background information: demographic, cognitive function, physical health, as well as on loneliness. Written informed consent was obtained at pre-intervention interview. Participants were also interviewed at the end of the intervention about six months after the baseline pre-intervention interviews (5.65(1.55) with a range of 3.20–9.00 months), and at end of a three-month follow-up period (3.09(.31) with a range of 2.40–4.07 months).

The study was conducted in three waves, and in each, we went through all the stages of the study including assessments, intervention, and control groups. At the end of the intervention process, the participants completed the assessment, and they were asked again to do so at the end of the three months' follow-up period. Post-intervention questionnaires were administered by a research assistant who was not associated with the interventions, thus decreasing the likelihood of a social desirability bias.

**Intervention.** The I-SOCIAL intervention is based on findings from Cohen-Mansfield and Parpura-Gill (2007), which highlighted the role of barriers in producing and maintaining loneliness in older persons. The intervention focused on addressing psychosocial barriers, such as low social self-efficacy, and environmental barriers, such as lack of social opportunities in the vicinity of the older person. The intervention included: (1) identifying the barriers for the specific person; (2) up to ten individual meetings with an activities counselor, which focused on helping the person address personal barriers to social integration and included discussions concerning options for social contacts as well as using techniques and local resources to tackle the barriers (e.g., undertaking a mapping of social opportunities in the neighborhood using resources from local governments and senior centers); and (3) up to seven group sessions of participants and the activities counselors were held in order to provide opportunities to increase social competence by practicing social skills within a protected setting, and as a venue to discuss barriers and ways to address them. The participants chose whether to partake in the individual meetings, the group sessions, or both. The rationale for including both individual and group sessions was based on our pilot work that found that some lonely persons were not comfortable in groups or initially not willing to participate in groups, and that individual meetings would allow us to work on barriers and solutions particular to each individual. In contrast, the group sessions allowed participants to practice and share solutions with each other. The activities counselors in this study had at least a Bachelor's degree in the social sciences. Prior to the intervention, the activities

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