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Effects of 'participatory group-based care management' on wellbeing of older people living alone: a randomized controlled trial

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ABSTRACT

Background and objectives: More knowledge is needed of the effectiveness of complex interventions that aim to promote the wellbeing of older people. This study examines the effects of 'participatory group-based care management' conducted among community-dwelling older adults living alone in Central and Eastern Finland. The intervention aimed to promote wellbeing and quality of life (QoL) using a needs-based and participatory approach.

Methods: The study was carried out as a randomized control trial (intervention group n = 185, control group n = 207). In this article, baseline and 6-month follow-up surveys were used. QoL (WHOQOL-Bref instrument), loneliness (Revised UCLA Loneliness Scale; single-item question), and trust (two items of generalized trust and six items of institutional trust) were used as outcome measurements, and generalized estimating equations (GEE) modeling as the analysis method. Both per-protocol and intention-to-treat analyses were applied.

Results: According to the per-protocol analysis, the intervention had no effects on QoL. Loneliness decreased among older people with poor QoL at the baseline. Additionally, the intervention enhanced trust in other people and some dimensions of institutional trust. The intention-to-treat analysis did not result in any significant effects on QoL or loneliness, but some small positive changes in institutional trust were found.

Conclusions: Based on some evidence of small positive effects, the intervention may be beneficial in alleviating loneliness and enhancing trust among older people living alone. Because of the contradictory results, more research is needed to examine the complexity of 'participatory group-based care management´ from the perspective of process evaluation.

1. Introduction

Effective strategies and models are needed to respond to the different needs of older adults (Suzman, Beard, Boerma, & Chatterji, 2015), and to reach people in vulnerable life situations (Whitehead, Povall, & Loring, 2014). Living alone has been considered to be a potential health risk (Kharicha et al., 2007). Older people living alone have a higher risk of social isolation (Victor, Scambler, Bowling, & Bond, 2005), as well as different forms of social exclusion (Walsh, Scharf, & Keating, 2017).

Many community-based interventions and services have been developed to support older people, particularly to enhance their social wellbeing (e.g. Gardiner, Geldenhuys, & Gott, 2018; Grenade & Boldy, 2008). At the same time, interest towards the effectiveness of these interventions has increased. A systematic review identified some general characteristics of effective interventions targeting social isolation in later life: having a theoretical basis, using a group format, and involving older people as active participants (Dickens, Richards, Hawton et al., 2011). Cattan, White, Bond, and Learmouth (2005) also note in their review that group interventions targeted at specific groups and incorporating educational or social activities are likely to be beneficial in alleviating loneliness and social isolation. Another review reported similar results concerning the effectiveness of educational group interventions, which included the aspect of promoting self-management abilities related to wellbeing (Cohen-Mansfield & Perach, 2015). Moreover, Gardiner et al. (2018) found in their review that interventions succeeded better when service users were involved in the planning and implementation of interventions.

Previous studies have indicated that group-based social interventions can cause various effects on older people's wellbeing. For example, Saito, Kai, and Takizawa (2012) found that a group-based educational intervention that aims to prevent social isolation is

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effective in terms of loneliness, familiarity with services, and informal social support. Social integration (Pynnönen, Törmäkangas, Rantanen, Tiikkainen, & Kallinen, 2018) and social participation (Coll-Planas et al., 2017) have also been found to be positive effects of group interventions for older people. On the other hand, several group interventions have been proved to be ineffective for any aspect of wellbeing, or the quality of the evidence is weak (see Cattan et al., 2005).

Some limited positive evidence of the effectiveness of social interventions that focus on one-to-one support has been found. (Cohen-Mansfield & Perach, 2015). For example, Cattan et al. (2005) argued that one-to-one befriending helps ameliorate the worst aspects of social isolation and exclusion. Cohen-Mansfield et al. (2018) successfully combined individual and group sessions to alleviate loneliness by addressing older people´s barriers to social contacts and increasing their self-efficacy. Gardiner et al. (2018) also found effective interventions that were not based only on a group method but also on productive activities, which means doing things together and being an active member of the group. By contrast, in the UK, a 12-week one-to-one community mentoring service that aimed to engage clients in meaningful social activities was not effective in any measured outcomes such as health status, social activity, or depression (Dickens, Richards, Greaves, & Campbell, 2011). A growing body of social interventions for older people can be found, but the methods and study design vary a lot, and the findings are often contradictory and inconclusive (e.g. Dickens, Richards, Hawton et al., 2011; Gardiner et al., 2018).

In addition to the need for social support, older people seem to need more counseling and advice in managing the social and healthcare system and receiving appropriate support and services (Tiilikainen, Hujala, Kannasoja, Rissanen, & Närhi, 2019). Care management (also known as case management) has been an important approach that aims to meet the needs of older people by coordinating care and services for them (Judd & Moore, 2011). The effectiveness of traditional community care management has been examined from different perspectives, such as the clients' quality of life (QoL) or service use (e.g. Reilly et al., 2015; You, Dunt, & Doyle, 2013).

Despite being the practice method for supporting older people living at home, preventive and social supportive models of care management have also recently been developed. A model of one-year care management with multiple home visits was developed and examined in Sweden. In addition to basic care management tasks, one aim of the model was to strengthen older people's social participation and leisure activities. A randomized controlled study indicated no effects on social participation, but some effects were found on performance of leisure activities (Granbom, Kristensson, & Sandberg, 2017). Additionally, the case management intervention had some limited effects on loneliness, life satisfaction, and depressive symptoms (Taube, Kristensson, Midlöv, & Jakobsson, 2018). In Australia, the 'Lifestyle Engagement Activity Program' was established with the aim of enhancing case managers' competence to invest in the social wellbeing of older clients. Case managers were trained to include social or recreational goals in care plans, while care workers concentrated more on supporting the personal resources of clients, to engage them in achieving the goals. After the 12-month intervention, older people showed an increase in client engagement and a decrease in apathy, dysphoria, and agitation (Low et al., 2015).

However, research knowledge of the effectiveness of complex social interventions for older people, especially in controlled trials, has been scarce. In addition, group-based care management models have hardly been developed and examined at all, even though previous studies have shown the positive results of group-based educational interventions. A preventive intervention called 'participatory group-based care management' was developed in Finland to address the social and service-related needs of community-dwelling older people who live alone and manage in their daily activities but have some challenges to their wellbeing. The overall aim of the intervention was to empower positive transitions in the target group's QoL and wellbeing.

The aim of this study is to examine the effects of 'participatory group-based care management' on older people's QoL. In addition to the primary outcome of QoL, changes in loneliness and trust were examined. These secondary outcomes were selected based on current policy interests toward addressing loneliness and supporting social cohesion, as well as the key elements and aims of the intervention. Compared to loneliness, less is known how different interventions impact trust, which has been referred to as one indicator of social cohesion (Schmeets & Riele, 2014). Here, both institutional and generalized trust were measured.

2. Methods

2.1. Design

The study is part of a Finnish consortium project called *Inclusive Promotion of Health and Wellbeing (PROMEQ)* (2016–2019). The central idea of PROMEQ has been to develop and demonstrate novel models of promoting health and wellbeing for people that the current methods do not seem to reach. One key target group has been older people living alone and at risk of different forms of exclusion. In the first phase of the study, focus group discussions were conducted with older persons living alone and experiencing some form of health or wellbeing deficit. Two clear themes were present in the discussions: loss of social connectedness and difficulties in gaining access to health and social care services and information regarding them (Tiilikainen et al., 2019). On the basis of these findings, an intervention model of 'participatory group-based care management' was designed in collaboration with local health and social care professionals. To examine the wellbeing effects of the intervention, the study was designed as a randomized controlled trial for six months.

Participants were recruited via local care managers and professionals working in local NGOs. Invitations to participate in the study were also sent out using traditional communication channels, such as local newspapers and radio, and by distributing leaflets in local healthcare centers and pharmacies. The invitation letter included information about the inclusion criteria, which were set at the beginning of the study: age 65+, full-time retirement, living alone, expression of at least one form of health and wellbeing deficit, and the use of health and social services at least twice in the last six months. In addition, the invitation letter contained detailed information about the research protocol, including a description of the randomization process.

The number of older people who enrolled in the study, explanations for dropouts and exclusions, and the study design are shown in Fig. 1. The target sample size was 360, which was considered a sufficient number based on previous research with similar study designs and analyses. A total of 392 older people responded to the baseline survey. Most of the participants filled in the survey independently, but some were interviewed face-to-face or by telephone. After the baseline survey, participants were randomized into an intervention group (n = 185) and a control group (n = 207). The randomization was carried out by members of the research group in lots of 16 or more participants. Only a few persons declined to participate in the intervention, and they were transferred to the control group. Participants belonging to the control group were not offered any services, but they were told to contact their local standard social and healthcare if they needed counseling, support, or services.

The drop-out rate was 6.1 % with reference to the participants who responded to the baseline survey but did not continue in the study during the six-month follow-up period (n = 24). Some participants were excluded from the per-protocol analysis because of their age (under 65 years) and limited participation in group meetings (n = 23). Finally, 345 (intervention n = 159, control n = 186) older persons were accepted into the per-protocol analysis, while all the randomized participants were included in the intention-to-treat analysis.

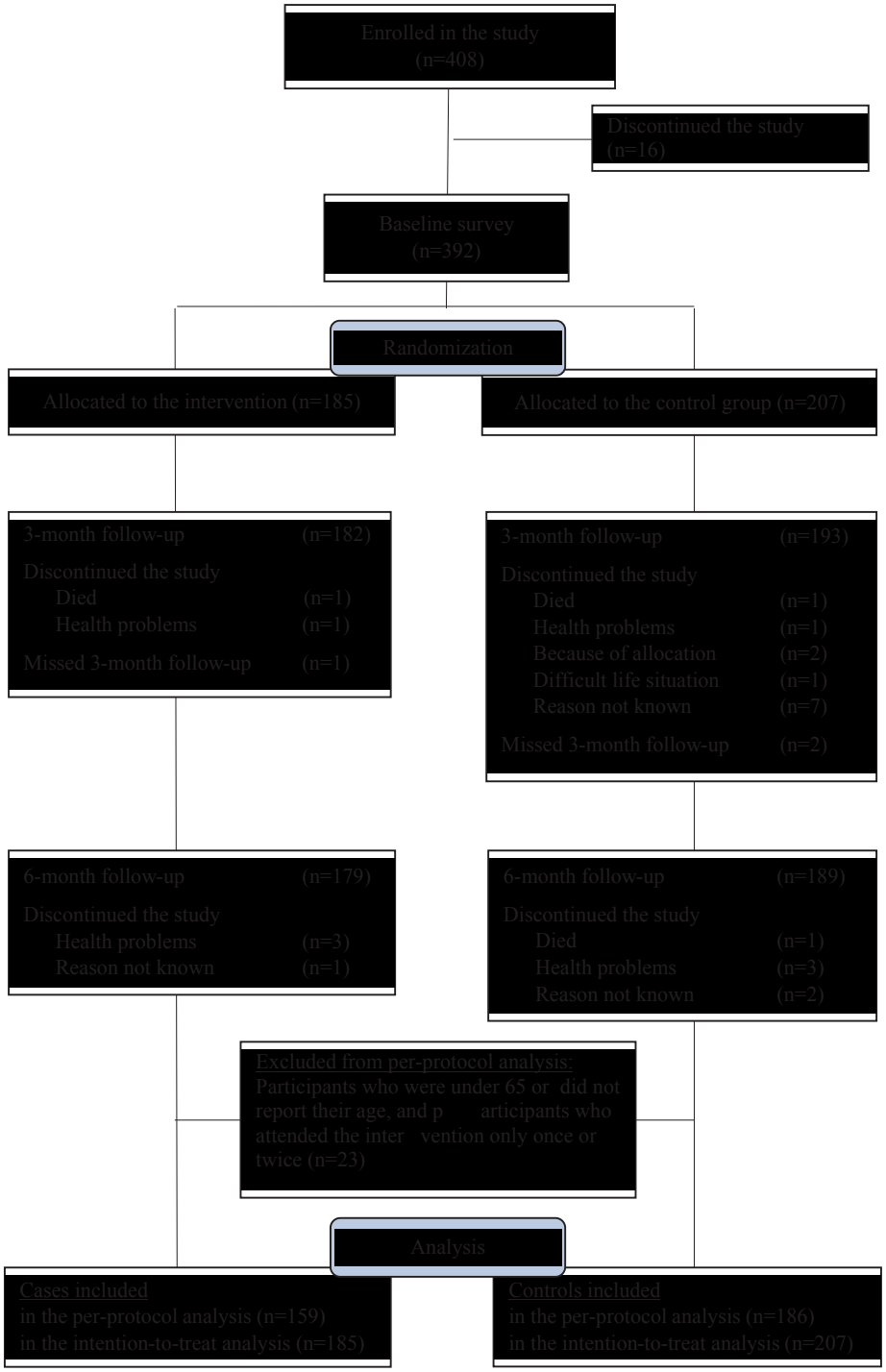

Fig. 1. Trial profile.

2.2. Intervention

The 'participatory group-based care management' was carried out in group meetings. The aim of the intervention was to enhance QoL and wellbeing using a participatory and needs-based approach. The intervention was designed especially to address the needs of older people living alone (in a private home) and experiencing some form of health or wellbeing deficit, and hence at risk of social exclusion (Walsh et al., 2017). The key elements of the intervention were: i) social support, ii) counseling, and iii) activities, where counseling refers to the promotive and preventive aspects of care management (e.g. Granbom et al., 2017; Low et al., 2015). During the six-month period, groups of 6–9 older persons attended five group meetings. Each group meeting lasted 2–3 hours and was facilitated by a care manager and a researcher. The participants were also encouraged to meet independently between the facilitated group meetings and after the six-month intervention.

The participants were involved in planning the contents of the group meetings. Each group meeting combined the three key elements (*social support*, *counseling*, and *activities*). Within the context of the intervention, *social support* refers to the possibility to share life experiences and socially interact with others via thematic and informal discussions and shared activities. *Counseling* includes information and

discussions concerning social and healthcare services (e.g. home care), other services (e.g. physical training services), local events (e.g. concerts, open lectures), health and wellbeing (e.g. nutrition, memory), and other topics (e.g. voluntary work, security). Counseling and guidance were provided by care managers and other specialists (e.g. dietician, third-sector coordinator), and also among the older people themselves. Counseling was provided using a dialogical and reciprocal approach. *Activities* included visits (e.g. swimming hall, museums, and library), outdoor gatherings, group exercises, and other recreation (e.g. having lunch together, playing board games) and were intended to support participation in the local environment. The intervention covered costs for the activities and provided transportation for older people who were not able to participate in the group meetings by their own means.

Examples of the group meetings:

Example 1. Day center and home support services: Exploring the environment of a day center and guidance about activities; coffee and catching up; discussion and information about home support services.

Example 2. Outdoor trip by a campfire: Catching up; a short stroll together; information about upcoming events and discussions about nature and outdoor activities; snacks and coffee; light workout and stretching.

2.3. Measurements

QoL was measured using the 26-item form of the WHO Quality of Life-BREF (WHOQOL-Bref) instrument (WHO, 2006). This was developed to assess an individual's perceptions in the context of their culture and value systems, and their personal goals, expectations, standards, and concerns. The instrument measures four broad domains: physical health (DOM1), psychological health (DOM2), social relationships (DOM3), and environment (DOM4) (WHOQOL Group, 1998). Participants were able to answer all the items about how they felt during the last two weeks on a 5-point Likert scale, indicating how good, how satisfied, how much, how completely, and how often. Responses to each domain were converted to a 0–100 scale: a higher score indicating a higher QoL. The WHOQOL-Bref was used both to examine the effects of the intervention and to split the sample into two subgroups. Reliability of the WHOQOL-Bref was tested using Cronbach's alpha (DOM1 = 0.819; DOM2 = 0.831; DOM3 = 0.692; DOM4 = 0.784).

Loneliness was measured using the 12-item form of the Revised UCLA Loneliness Scale (Russel, 1996). The UCLA scale was designed to measure both one's subjective feelings of loneliness and feelings of social isolation (Russel, Peplau, & Ferguson, 1978). The 12-item UCLA scale is a Finnish version (Junttila et al., 2013) that is modified from the original 20-item scale. The scale included items such as "I am no longer close to anyone," and the response options were: "never", "rarely", "sometimes", and "often feel this way". Ratings were counted to generate an average loneliness score ranging from 1 to 4, with a higher score expressing greater loneliness. Cronbach´s alpha for the UCLA scale is 0.912. In addition, the participants were asked a self-rated single-item question "Do you feel lonely?" The response options were: "never", "very rarely", "sometimes", "fairly often", and "all the time".

Trust was measured using two statements of generalized trust and six statements of institutional trust. A variety of scales for measuring generalized trust exists (Lundmark, Gilljam, & Dahlberg, 2016). In this study, we used statements: "In our society, people can trust one another" (trust in other people) and "it is best to not trust anyone" (mistrust). Items of institutional trust were related to trust in several societal institutions: the government and public authority, public healthcare, public social care, a court of law, police, and municipal decision-making. In responses to trust statements, a 5-point Likert scale was used. Response options were: "I completely agree", "I somewhat agree", "I do not agree or disagree", "I somewhat disagree", and "I completely disagree". Apart from the statement of mistrust, the scales were reversed. A higher score indicates greater levels of trust. The sum variable of institutional trust was used with an average score, which was consistent with the original scale. Cronbach's alpha for the sum variable of institutional trust is 0.844.

Background information such as year of birth, gender, education, type of accommodation, and income (per year) was also requested in the questionnaire. In addition, the survey included other measurements for wellbeing, health, health behavior, service use, and modes of life. These measurements were not used in this study.

2.4. Statistical analysis

In this experimental study, piloting and examining the novel intervention, no sample size calculation was performed. The comparison of intervention and control groups at the baseline was conducted using statistical tests (Pearson chi-square test for categorical variables, and two-sample t-test or Mann Whitney U-test for continuous variables). The same tests were used when comparing dropouts and excluded participants to the population included in the per-protocol analysis.

A longitudinal regression with generalized estimating equations (GEE) models was used to estimate parameters for group (G) and time (T) effects, and also group-by-time (GxT) interaction (Zeger & Liang, 1986). The interaction between group and time shows whether changes over time differ in the control and intervention groups. The model type used was linear with an identity link function. Model parameters were estimated for the four domains of QoL, loneliness, and trust. We report sample means and standard deviations of outcome variables and the type III overall effects (group, time, and group-by-time). All statistical tests were considered as significant at the P value level 0.05. Effect sizes were calculated using Cohen's d for all outcomes. Endpoint change means and standard deviations were used in computing the effect sizes (ES). A common rule was applied for determining 0.20 as a small effect, 0.50 as a medium effect, and 0.80 as a large effect (McGough & Faraone, 2009).

The analyses were conducted within the whole sample and in subgroups according to the level of QoL at the baseline. A cut-off point of 60 was used when splitting the sample into groups of poor QoL and good QoL. Previous research has indicated that this is an optimal cut-off point when a division is needed (Silva, Soares, Santos, & Silva, 2014). Subgroup analyses were conducted because the intervention was originally planned for older people who have challenges with their health and/or wellbeing. By exploring the effects within particular groups, it is possible to evaluate whether the intervention was effective for people with poor QoL or people with good QoL.

The analyses were performed primarily according to the per-protocol principles by excluding both dropouts and those who did not complete the intervention. The per-protocol approach indicates the efficacy of the intervention in causing the desired outcomes. It provides information on whether the intervention is effective for those who really receive the intervention (Shier, Verhagen, & Stovitz, 2017). The per-protocol approach is relevant when the objective of the study is explanatory (Armijo, Warren, & Magee, 2009). Thus, conducting only per-protocol analysis can lead to biased results, which was taken into account by comparing the excluded cases to the sample included in the analysis (Bennet, 2001). Missing data of individual variables were dealt with using the method of available case analysis. Missing data varied for individual variables between 0.3 % and 1.9 %.

In addition to the per-protocol approach and following the CONSORT statement (Moher et al., 2010), intention-to-treat analyses were carried out. The intention-to-treat protocol means analyzing the whole sample in the groups in which they were originally randomized. Intention-to-treat analysis estimates the population level average causal effect, indicating the effectiveness of the intervention in real-world settings (Armijo-Olivo et al., 2009; Shier et al., 2017). The assumption for missing data was MAR (missing at random), which required using

MI-based GEE modeling (Aloisio, Micali, Swanson, Field, & Horton, 2014; White, Horton, Carpenter, & Pocock, 2011). Predictive mean matching with 20 iterations was used as the method of multiple imputation.

Analyses were conducted using the Statistical software package (SPSS, versions 23 and 25) and StataIC 15 (64-bit).

2.5. Ethical considerations

The study was carried out with the approval of the University of Eastern Finland Committee on Research Ethics and the municipalities participating in the trial. Written informed consent was obtained from all participants before data collection. All data has been treated confidentially.

The CONSORT 2010 statement (Moher et al., 2010; Schultz, Altman, & Moher, 2010) and the CONSORT extension for social and psychological interventions (Grant et al., 2018) were utilized when reporting the study.

3. Results

At the baseline, the average age of the participants was 76.8 years, ranging between 60 and 99 years. Most of the participants (82.9 %) were women. No significant differences were found between the intervention and control groups (for the randomized sample or for the participants included in the per-protocol analysis) regarding background information such as age, gender, or socioeconomic status and the outcome variables QoL, loneliness, or trust (Table 1).

3.1. QoL, loneliness, and trust (per-protocol)

The intervention had no overall effect on QoL in any domains (physical health, psychological health, social relationships, and environment) or in total QoL. However, the time effect was statistically significant for DOM4 (p = .038), indicating increased environmental QoL in both the intervention and control groups. Loneliness also decreased over time, according to both the UCLA Loneliness Scale and the single-item question (Table 2).

When analyzing the other outcome measurements, two statistically significant differences between the intervention and control groups were found in single variables of trust. Trust in other people (GxT p = .050, ES = .21) and trust in government and public authority (GxT p = .015, ES = .26) increased in the intervention group, while they decreased in the control group (Table 2).

3.2. Subgroup and supplementary analyses

For more detailed results of effects within particular groups of participants, two subgroups were constructed based on the measurement of QoL (WHOQOL-Bref). In all, 44.4 % assessed their QoL as poor based on a cut-off point of 60 (scale 0–100). No statistically significant differences in age, gender, education, or income between the control and intervention groups inside the subgroups for QoL appeared. When examining the effects of the intervention in subgroups of poor and good QoL, some statistically significant differences were found. In the subgroup of participants with poor QoL, loneliness (UCLA) decreased (GxT p = .034, ES = .35), and trust in public social care enhanced (GxT p = .011, ES = .44) in the intervention group. However, the intervention and control groups of participants with poor QoL were not fully comparable in terms of loneliness, because baseline values differed between the intervention and control groups (Table 3).

In the subgroup of participants with good QoL, two statistically significant differences in group-by-time interaction were found in variables of trust. Trust in other people (GxT p = .018, ES = .34) and trust in municipal decision-making (GxT p = .017, ES = .35) increased in the intervention group and decreased in the control group. Despite increased trust as presented above, participants with good QoL trusted the police less at the six-month measurement compared to the baseline measurement in both the intervention and control groups (Time effect p = .017). In addition, single-item measured loneliness decreased in the intervention and control groups over time for those with poor QoL (Time effect p = .001) and good QoL (Time effect p = .012). Also changes in QoL over time in both subgroups were found (Table 3).

The population included in the per-protocol analyses (n = 345) was compared to dropouts and excluded participants (n = 47). At the baseline, the groups did not statistically significantly differ in age, gender, income, education, QoL (total), loneliness, or institutional trust. However, physical QoL was better among participants included in the analysis (mean 58.3, SD 17.3) compared to those who were excluded (mean 54.0, SD 17.2). There were also differences in environmental

Table 1
Baseline characteristics of the participants and a comparison between the intervention and control groups for the randomized sample and for the per-protocol sample.

Variable	Randomized sample (n = 392)	Intervention (n = 185)	Control (n = 207)	Comparison (p-values)	Per-protocol sample (n = 345)	Comparison (per-protocol, p-values)
Age (M)	76.8 (SD 7.5)	76.8 (SD 7.2)	76.8 (SD 7.76)	.877[a]	76.8 (SD 7.3)	.952[a]
Gender (female)	325 (82.9 %)	152 (82.2 %)	173 (83.6 %)	.711[b]	290 (84.1 %)	.434[b]
Education (n)				.445[b]		.445[b]
- Basic	124 (31.6 %)	54 (29.2 %)	70 (33.8 %)		110 (31.9 %)	
- Secondary	184 (46.9 %)	93 (50.3 %)	91 (44.0 %)		163 (47.2 %)	
- High	84 (21.4 %)	38 (20.5 %)	46 (22.2 %)		72 (20.9 %)	
Income (n)	*			.169[b]	**	.197[b]
< 15000	113 (28.8 %)	45 (25.3 %)	68 (33.8 %)		98 (29.2 %)	
15001 – 35000	225 (57.4 %)	114 (64.0 %)	111 (55.2 %)		200 (59.5 %)	
35000 >	41 (10.5 %)	19 (10.7 %)	22 (10.9 %)		38 (11.3 %)	
QoL (M)	61.0 (SD 13.4)	61.3 (SD 13.7)	60.8 (SD 13.1)	.744[c]	61.3 (SD 13.3)	.535[c]
Loneliness						
- UCLA (M)	2.0 (SD 0.6)	2.0 (SD 0.6)	2.0 (SD 0.6)	.233[c]	2.0 (SD 0.6)	.177[c]
- Single-item (M)	3.0 (SD 1.1)	3.0 (SD 1.0)	3.0 (SD 1.1)	.882[c]	3.0 (SD 1.0)	.899[c]
Generalized trust						
- Trust in other people (M)	3.2 (SD 1.0)	3.1 (SD 1.0)	3.2 (SD 1.0)	.916[c]	3.2 (SD 1.0)	.724[c]
- Mistrust other people (M)	3.5 (SD 1.2)	3.5 (SD 1.2)	3.5 (SD 1.2)	.947[c]	3.6 (SD 1.2)	.896[c]
Institutional trust (M)	3.5 (SD 0.8)	3.5 (SD 0.8)	3.5 (SD 0.8)	.845[c]	3.5 (SD 0.8)	.990[c]

* Missing 13.
** Missing 9.
[a] Mann Whitney U-test.
[b] Pearson Chi-Square test.
[c] Two sample t-test.

Table 2
Means, standard deviations, and generalized estimating equations (GEE) model parameters for time, group, and group-by-time interaction for QoL, loneliness, and trust, according to the per-protocol analysis.

Variable	Intervention group (n = 159)		Control group (n = 186)		Sig.*			ES**
	BL	6m	BL	6m	Time	Group	GxT	
QoL (total)	61.8 (13.3)	62.2 (13.4)	60.9 (13.3)	60.7 (13.9)	.942	.399	.611	.05
- Physical (DOM1)	59.8 (16.8)	59.7 (16.9)	57.0 (17.7)	56.2 (19.3)	.465	.074	.768	.03
- Psychological (DOM2)	59.6 (16.9)	59.2 (16.5)	59.6 (16.2)	60.0 (15.6)	.967	.829	.512	.07
- Social (DOM3)	62.6 (19.4)	62.9 (18.5)	62.8 (20.5)	61.5 (21.4)	.589	.852	.309	.12
- Environment (DOM4)	64.7 (14.9)	66.6 (14.8)	63.8 (17.2)	64.7 (15.8)	**.038**	.373	.544	.06
Loneliness								
- UCLA	2.0 (0.6)	1.9 (0.6)	1.9 (0.6)	1.9 (0.6)	**.001**	.230	.333	.11
- Single-item	3.0 (0.9)	2.7 (1.0)	3.0 (1.0)	2.8 (1.0)	**.000**	.632	.301	.12
Generalized trust								
- Trust in other people	3.2 (1.0)	3.3 (0.9)	3.2 (1.0)	3.2 (1.0)	.188	.443	**.050**	**.21**
- Mistrust other people	3.6 (1.1)	3.5 (1.2)	3.6 (1.2)	3.5 (1.2)	.171	.989	.864	.01
Institutional trust	3.5 (0.7)	3.6 (0.7)	3.5 (0.8)	3.4 (0.8)	.488	.456	.132	.16
- Government and pa	3.2 (1.1)	3.3 (1.0)	3.2 (1.2)	3.0 (1.2)	.154	.185	**.015**	**.26**
- Public health care	3.5 (1.0)	3.5 (1.0)	3.6 (1.1)	3.6 (1.0)	.493	.477	.835	.02
- Public social care	3.2 (1.0)	3.3 (0.9)	3.3 (1.1)	3.2 (1.0)	.334	.804	.115	.17
- Court of law	3.7 (1.1)	3.7 (0.9)	3.7 (1.2)	3.7 (1.1)	.829	.615	.869	.02
- Police	4.2 (0.8)	4.1 (0.9)	4.1 (1.0)	4.0 (1.0)	**.009**	.219	.951	.01
- Municipal dm	3.2 (0.9)	3.3 (0.8)	3.2 (1.1)	3.1 (1.0)	.891	.217	.245	.12

* P-values for type III GEE model effects tested using the Wald Chi-Square test, indicating significance at the level 0.05.
** Effect size (Cohen's d).

QoL between the included (mean 64.2, SD 16.2) and excluded participants (mean 59.5, SD 14.4). A larger proportion of the excluded participants felt lonely fairly often or all the time (38.3 %) than those who were included in the analysis (30.2 %). At the baseline, generalized trust was statistically significantly lower among the excluded participants.

Intention-to-treat analyses were carried out similarly for the whole sample and for subgroups of QoL. Within the whole sample, intention-to-treat analyses resulted in one statistically significant group-by-time interaction effect in the single variable of trust in government and public authorities (GxT p = .022) (Appendix A). No statistically significant changes in any of the outcomes when comparing the intervention and control groups after the intervention with the subgroup with poor QoL were found. Despite that, the intervention had a statistically significant effect on trust in municipal decision-making (GxT p = .021) among the participants with good QoL (Appendix B).

4. Discussion

This study examined the effects of 'participatory group-based care management' on QoL, loneliness, and trust among older people living alone. The results showed that the intervention did not have an effect on the QoL of the study participants. However, according to the per-protocol analysis, the intervention had some positive effects on loneliness and trust when measured right after the intervention. The per-protocol approach indicates the efficacy of the intervention in optimal circumstances. From a client-oriented perspective, it takes into account the effects for those people who participated in the intervention (Armijo-Olivo et al., 2009). The results of per-protocol analysis do not provide much information about the effectiveness of the intervention in the real world. By contrast, the intention-to-treat method is a population-level approach that shows the effectiveness of the intervention in the real world based on unbiased results (e.g. White et al., 2011). When utilizing the intention-to-treat protocol, no effects on loneliness were found, and the effects on trust either disappeared or were smaller than indicated by the results of the per-protocol analyses. However, when examining a new intervention, it is important to find out whether the intervention works at all. Therefore, the results of per-protocol analyses are explored and discussed carefully.

According to the per-protocol analysis and the UCLA scale, the intervention reduced loneliness in older people with poor QoL at the baseline. However, no changes appeared in the single-item question of loneliness. Older people with poor QoL experience loneliness more often than those with good QoL (Table 3). Thus, positive changes in loneliness were more likely to happen in this particular subgroup. These findings are in line with previous contradictory results on loneliness and social interventions (e.g. Dickens, Richards, Hawton et al., 2011; Gardiner et al., 2018). Moreover, the findings support the project's overall aim of particularly supporting the wellbeing of older people living in vulnerable life situations. In terms of this aim, the intervention was successful and effective within the social dimension of wellbeing. Even though the intervention was not originally developed for tackling loneliness, one of its key aims was to provide social support between group participants and to support participation in local environments and communities. Burholt, Windle, and Morgan (2017) argue that the social environment could have an underestimated effect on loneliness. For example, public attitudes toward aging may decrease older people's participation in activities and society. The intervention might have offered the participants a feeling of being respected and recognized by others.

Aspects of social inclusion and cohesion may also be examined from the perspective of trust, which was divided into social and institutional trust in our analysis. Social trust was measured as generalized trust (Delhey & Newton, 2003), referring to how much people trust each other, especially those they do not know (e.g. Rothstein & Stolle, 2008). The intervention had an effect on generalized trust, mostly among older people with good QoL at the baseline. Generalized trust is known to have a positive impact on subjective wellbeing, as a sense of togetherness is important for the existence of trust (see Delhey & Dragolov, 2013). Our understanding is that the study participants may have felt a sense of togetherness during the intervention, which could partly explain the increased generalized trust. Institutional trust states how much people trust in institutions and other formal actors in society. Our study indicates some evidence of the possibility of the group intervention to enhance institutional trust, according to both per-protocol and intention-to-treat analysis.

Together, social relationships and trust could represent the concept of security and feelings of safety in later life. In Finland and Sweden, older people's sense of security is related to meaningful life and trust in economic institutions. On the other hand, feelings of insecurity are connected to weak trust in family, friends, or neighbors (Fageström, Gustafson, Jakobsson, Johansson, & Vartiainen, 2011). Effects on

Table 3
Means, standard deviations, and GEE model parameters for time, group, and group-by-time interaction for QoL, loneliness, and trust among subgroups of poor and good QoL, according to the per-protocol analysis.

Poor QoL (n = 150)

Variable	Intervention (n = 64)		Control (n = 86)		Sig.*			ES**
	BL	6m	BL	6m	Time	Group	GxT	
QoL (total)	49.0 (8.5)	52.7 (11.5)	49.7 (7.9)	51.9 (10.7)	**.000**	.951	.335	.16
- Physical (DOM1)	48.6 (15.2)	51.6 (14.6)	46.5 (15.7)	48.3 (17.7)	**.049**	.241	.620	.10
- Psychological (DOM2)	45.8 (14.8)	48.5 (15.4)	49.1 (13.9)	52.0 (14.4)	**.003**	.122	.920	.02
- Social (DOM3)	48.4 (18.8)	53.2 (18.7)	51.2 (19.0)	51.8 (21.1)	.055	.800	.132	**.24**
- Environment (DOM4)	53.3 (10.5)	57.3 (12.5)	51.8 (14.0)	55.4 (13.6)	**.000**	.367	.852	.02
Loneliness								
- UCLA	2.5 (0.6)	2.4 (0.6)	2.2 (0.6)	2.2 (0.6)	**.001**	**.006**	**.034**	**.35**
- Single-item	3.6 (0.8)	3.2 (0.8)	3.4 (1.0)	3.2 (1.0)	**.000**	.580	.348	.16
Generalized trust								
- Trust in other people	3.0 (0.9)	3.1 (0.9)	3.0 (1.0)	3.0 (1.1)	.461	.679	.552	.09
- Mistrust other people	3.1 (1.1)	3.1 (1.2)	3.4 (1.2)	3.4 (1.2)	.862	.056	.862	.02
Institutional trust	3.2 (0.7)	3.3 (0.7)	3.2 (0.8)	3.1 (0.8)	.849	.456	.177	**.23**
- Government and pa	2.9 (1.1)	3.0 (0.9)	2.8 (1.1)	2.6 (1.2)	.312	.164	.060	**.31**
- Public health care	3.1 (1.0)	3.2 (1.0)	3.4 (1.0)	3.3 (1.1)	.832	.201	.304	.17
- Public social care	2.8 (0.9)	3.1 (0.9)	3.0 (1.0)	2.9 (1.1)	.420	.979	**.011**	**.44**
- Court of law	3.3 (1.2)	3.4 (1.0)	3.3 (1.2)	3.3 (1.2)	.509	.713	.813	.05
- Police	4.0 (0.7)	4.0 (0.8)	3.8 (1.2)	3.7 (1.1)	.411	.078	.608	.09
- Municipal dm	3.1 (0.9)	3.1 (0.9)	2.8 (1.0)	3.0 (0.9)	.257	.123	.463	.13

Good QoL (n = 188)

Variable	Intervention (n = 92)		Control (n = 96)		Sig.*			ES**
	BL	6m	BL	6m	Time	Group	GxT	
QoL (total)	70.7 (7.6)	68.6 (10.8)	70.9 (8.1)	68.6 (11.5)	**.000**	.939	.801	.04
- Physical (DOM1)	67.8 (12.9)	65.1 (16.5)	66.6 (13.4)	63.7 (17.9)	**.003**	.521	.934	.01
- Psychological (DOM2)	69.4 (10.2)	66.7 (12.9)	69.4 (11.6)	67.2 (13.1)	**.002**	.882	.750	.05
- Social (DOM3)	72.5 (12.4)	70.0 (15.1)	73.0 (15.4)	69.6 (17.5)	**.005**	.948	.695	.05
- Environment (DOM4)	72.9 (11.8)	72.7 (13.2)	74.6 (11.0)	73.3 (12.1)	.284	.460	.450	.11
Loneliness								
- UCLA	1.7 (0.4)	1.6 (0.5)	1.7 (0.5)	1.6 (0.5)	.312	.991	.983	.01
- Single-item	2.6 (0.9)	2.4 (1.0)	2.6 (0.9)	2.5 (1.0)	**.012**	.620	.281	.16
Generalized trust								
- Trust in other people	3.3 (1.0)	3.6 (1.0)	3.5 (0.9)	3.4 (0.9)	.278	.945	**.018**	**.34**
- Mistrust other people	4.0 (1.1)	3.9 (1.1)	3.8 (1.2)	3.7 (1.2)	.151	.231	.973	.01
Institutional trust	3.7 (0.6)	3.7 (0.6)	3.8 (0.7)	3.7 (0.7)	.330	.599	.377	.10
- Government and pa	3.4 (1.0)	3.5 (1.0)	3.5 (1.1)	3.3 (1.1)	.354	.959	.106	**.23**
- Public health care	3.8 (0.9)	3.8 (0.8)	3.8 (1.1)	3.9 (0.9)	.400	.579	.409	.11
- Public social care	3.4 (0.9)	3.5 (0.8)	3.5 (1.0)	3.5 (0.9)	.541	.817	.906	.01
- Court of law	4.0 (0.9)	4.0 (0.9)	4.1 (0.9)	4.0 (0.9)	.196	.635	.888	.02
- Police	4.4 (0.8)	4.2 (0.9)	4.4 (0.8)	4.3 (0.8)	**.017**	.426	.638	.06
- Municipal dm	3.4 (0.9)	3.5 (0.8)	3.6 (0.9)	3.3 (0.9)	.349	.804	**.017**	**.35**

* P-values for type III GEE model effects tested using the Wald Chi-Square test, indicating significance at the level 0.05.
** Effect size (Cohen's d).

institutional and generalized trust might be consequences of counseling, which is a key element of the care management intervention. One of the main ideas of the intervention was to provide older people with information regarding services, as well as health and wellbeing promotion, based on their own needs. Almost all the intervention groups wanted to know more about social services supporting independent living at home. In addition to social support, the study participants considered the information gained during the intervention to be important. Based on the interviews with study participants (reported elsewhere), respondents thought that new knowledge of services increased their sense of security and trust in the future (Ristolainen et al., 2019).

Even though no effects were found on QoL, the results show that the intervention could have an effect on older people's wellbeing in different ways. The multidimensional and heterogeneous elements and contents of the intervention, as well as the needs-based approach, provide a possibility to take into account the different needs of older people living alone. Participatory group-based care management is a complex social intervention that offers different benefits for those in vulnerable life situations and those who are more in need of preventive support.

The small effects on loneliness and trust, and non-existent effects on QoL, call for the consideration of possible improvements to the intervention. Based on the qualitative data gathered during the intervention study, the time periods between the group meetings appeared too long for some participants. More frequent meetings, at least at the beginning of the intervention, might ease integration and communication within the group and enhance the participants' QoL more effectively. Another important aspect is the acknowledgment of difficulties in reaching older people with poor QoL, and the fact that they were more likely not to complete the intervention. Researchers and professionals working with older people are familiar with this issue, but they lack efficient ways of reaching people in difficult life situations. Group-based interventions would benefit from working closely with the different practices and services of "outreach work" to target those older people who are most at risk of isolation and poor QoL.

4.1. Limitations

Loneliness was measured using the Revised UCLA Loneliness Scale, which refers to the existence of social relationships and is based on distinguishing between social and emotional loneliness (Victor, Scambler, & Bond, 2009, 58–60). The Revised UCLA Loneliness Scale (20-item version) has been criticized when measuring the loneliness of older people, even though Russel (1996) stated its reliability and validity in all age groups. The UCLA scale was originally developed for young people (Victor et al., 2009, 58), and the Finnish version of the scale (12-item) used in this study was validated with the data of Finnish mothers and fathers with or expecting small children. As a result, the scale may not reveal enough regarding loneliness in later life.

Subgroup analyses were based on the original idea of targeting the intervention at older people with challenges to their wellbeing. Subgroup analyses were not predefined, but they were based on previous research on classifying people in the groups of poor and good QoL. Analyses were done by splitting the sample and conducting subgroup-specific analyses. This was possible because the subgroups were big enough and approximately the same size. In addition, the randomization was valid inside the subgroups in terms of background variables. However, the results of the subgroup analyses should not be overemphasized, because they are not based on the original study design (e.g. Brookes et al., 2001).

5. Conclusion

Even though evidence of the effects of 'participatory group-based care management' is contradictory, the intervention can benefit older people by reducing loneliness and enhancing some components of trust. The practices of care management should be developed to confront more efficiently older people's social and service-related needs, such as insecurity, loneliness, and lack of knowledge about services, as well as promoting health and wellbeing. In addition, more research is needed to evaluate the practices of care management in terms of preventive work and support of social wellbeing.

In the social sciences, research on the effectiveness of social interventions using the method of RCT is still quite marginal. This study may encourage researchers to set out to examine the effectiveness of complex social interventions. For a more detailed examination of the intervention's effects on loneliness and trust, it is suggested that the qualitative data collected during the project should also be analyzed. Using a mixed-method approach, it would be possible to evaluate the intervention process and to understand the causal mechanisms in more depth (Moore et al., 2015).

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CRediT authorship contribution statement

Hanna Ristolainen: Conceptualization, Methodology, Software, Validation, Formal analysis, Investigation, Resources, Data curation, Writing - original draft, Writing - review & editing, Visualization. **Sirpa Kannasoja:** Conceptualization, Methodology, Software, Validation, Investigation, Resources, Data curation, Writing - review & editing, Visualization. **Elisa Tiilikainen:** Conceptualization, Methodology, Software, Investigation, Resources, Data curation, Writing - review & editing, Visualization. **Mari Hakala:** Investigation, Resources, Data curation, Writing - review & editing. **Kati Närhi:** Conceptualization, Methodology, Investigation, Resources, Writing - review & editing, Supervision, Project administration, Funding acquisition. **Sari Rissanen:** Conceptualization, Methodology, Investigation, Resources, Writing - review & editing, Supervision, Project administration, Funding acquisition.

Declarations of Competing Interest

None.

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Appendix A. Means, standard deviations, and generalized estimating equations (GEE) model parameters for group-by-time interaction for QoL, loneliness, and trust, according to the intention-to-treat analysis

	Intervention group (n = 185)		Control group (n = 207)		Sig.
Variable	BL	6m	BL	6m	GxT
QoL (total)	61.2 (13.7)	61.5 (14.1)	60.5 (13.4)	60.4 (14.0)	.635
- Physical (DOM1)	58.7 (17.1)	58.6 (17.7)	56.8 (17.5)	55.9 (19.5)	.534
- Psychological (DOM2)	59.6 (17.0)	59.3 (17.0)	59.8 (16.4)	60.1 (15.9)	.607
- Social (DOM3)	62.2 (20.3)	62.5 (20.3)	62.3 (20.6)	61.3 (21.6)	.457
- Environment (DOM4)	64.1 (15.0)	65.7 (15.6)	63.1 (17.0)	64.2 (16.3)	.726
Loneliness					
- UCLA	2.0 (0.6)	2.0 (0.7)	2.0 (0.6)	1.9 (0.6)	.790
- Single-item	3.0 (0.9)	2.8 (1.0)	3.0 (1.1)	2.8 (1.1)	.308
Generalized trust					
- Trust in other people	3.1 (1.0)	3.3 (1.0)	3.2 (1.0)	3.2 (1.0)	.166
- Mistrust other people	3.5 (1.2)	3.5 (1.2)	3.5 (1.3)	3.5 (1.2)	.939
Institutional trust	3.5 (0.8)	3.5 (0.7)	3.5 (0.8)	3.4 (0.8)	.148
- Government and pa	3.2 (1.1)	3.3 (1.1)	3.1 (1.2)	3.0 (1.2)	**.022**
- Public health care	3.5 (1.0)	3.6 (1.0)	3.6 (1.1)	3.6 (1.1)	.741
- Public social care	3.2 (1.1)	3.3 (0.9)	3.2 (1.1)	3.2 (1.1)	.119
- Court of law	3.7 (1.1)	3.7 (0.9)	3.7 (1.2)	3.7 (1.1)	.989
- Police	4.2 (0.9)	4.1 (0.9)	4.2 (1.0)	4.0 (1.0)	.846
- Municipal dm	3.2 (1.0)	3.3 (0.9)	3.2 (1.1)	3.1 (1.0)	.115

Appendix B. Means, standard deviations, and generalized estimating equations (GEE) model parameters for group-by-time interaction for QoL, loneliness, and trust among subgroups of poor and good QoL, according to the intention-to-treat analysis

Poor QoL (n = 177–180*)					
Variable	Intervention group (n = 79–81)		Control group (n = 98–99)		Sig.
	BL	6m	BL	6m	GxT
QoL (total)	48.6 (8.7)	52.5 (12.5)	49.4 (8.0)	52.0 (11.2)	.390
- Physical (DOM1)	47.3 (15.0)	50.9 (12.3)	46.6 (15.3)	48.0 (17.8)	.321
- Psychological (DOM2)	45.9 (14.5)	49.4 (16.5)	48.9 (13.9)	52.5 (15.1)	.980
- Social (DOM3)	47.8 (19.3)	52.4 (20.7)	50.7 (19.2)	52.4 (21.5)	.318
- Environment (DOM4)	53.3 (10.1)	57.4 (12.9)	51.3 (14.0)	55.1 (14.4)	.868
Loneliness					
- UCLA	2.5 (0.6)	2.4 (0.6)	2.2 (0.6)	2.2 (0.6)	.542
- Single-item	3.5 (0.8)	3.3 (0.9)	3.4 (1.0)	3.2 (1.0)	.692
Generalized trust					
- Trust in other people	3.0 (0.9)	3.0 (0.9)	2.9 (1.0)	2.9 (1.1)	.895
- Mistrust other people	3.0 (1.1)	3.1 (1.2)	3.3 (1.2)	3.4 (1.2)	.917
Institutional trust	3.2 (0.7)	3.3 (0.7)	3.2 (0.8)	3.1 (0.8)	.211
- Government and pa	2.9 (1.1)	3.0 (1.0)	2.8 (1.2)	2.6 (1.2)	.096
- Public health care	3.2 (1.0)	3.2 (1.1)	3.3 (1.0)	3.3 (1.1)	.676
- Public social care	2.9 (0.9)	3.1 (0.9)	3.0 (1.0)	2.9 (1.1)	.080
- Court of law	3.3 (1.2)	3.4 (0.9)	3.3 (1.2)	3.3 (1.2)	.988
- Police	4.1 (0.8)	4.0 (0.9)	3.9 (1.1)	3.7 (1.1)	.444
- Municipal dm	3.0 (0.9)	3.1 (0.9)	2.8 (1.0)	2.9 (1.0)	.921

Good QoL (n = 212–214)					
Variable	Intervention group (n = 104–105)		Control group (n = 108–109)		Sig.
	BL	6m	BL	6m	GxT
QoL (total)	70.7 (7.5)	68.4 (11.0)	70.6 (8.3)	68.0 (11.9)	.848
- Physical (DOM1)	67.3 (12.9)	64.5 (17.1)	66.1 (13.8)	63.0 (18.3)	.911
- Psychological (DOM2)	70.1 (10.0)	66.9 (12.9)	69.6 (11.4)	67.1 (13.3)	.675
- Social (DOM3)	73.2 (12.9)	70.1 (16.3)	72.8 (15.7)	69.3 (18.7)	.861
- Environment (DOM4)	72.4 (12.6)	72.1 (14.2)	73.9 (11.3)	72.5 (13.1)	.500
Loneliness					
- UCLA	1.7 (0.4)	1.6 (0.5)	1.7 (0.5)	1.7 (0.5)	.686
- Single-item	2.6 (0.8)	2.4 (1.0)	2.6 (1.0)	2.5 (1.0)	.263
Generalized trust					
- Trust in other people	3.3 (1.1)	3.5 (1.0)	3.4 (0.9)	3.4 (0.9)	.067
- Mistrust other people	3.9 (1.1)	3.8 (1.2)	3.7 (1.2)	3.6 (1.3)	.993
Institutional trust	3.7 (0.7)	3.7 (0.7)	3.8 (0.7)	3.7 (0.7)	.409
- Government and pa	3.4 (1.0)	3.5 (1.1)	3.5 (1.1)	3.3 (1.1)	.109
- Public health care	3.8 (0.9)	3.8 (0.9)	3.8 (1.1)	3.9 (0.9)	.343
- Public social care	3.4 (1.1)	3.5 (0.8)	3.4 (1.0)	3.5 (1.0)	.689
- Court of law	4.0 (0.9)	4.0 (0.9)	4.0 (0.9)	4.0 (1.0)	.962
- Police	4.3 (0.9)	4.2 (0.9)	4.4 (0.8)	4.3 (0.9)	.630
- Municipal dm	3.4 (1.0)	3.5 (0.8)	3.6 (0.9)	3.3 (1.0)	**.021**

*Estimation samples varied across imputations because of the division according to QoL (poor/good QoL).

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