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The use of case management for community-dwelling older people: the effects on loneliness, symptoms of depression and life satisfaction in a randomised controlled trial

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Aim: To investigate the effects of a case management intervention for community-dwelling frail older people, with functional dependency and repeated contacts with the healthcare services, focusing on loneliness, depressive symptoms and life satisfaction.
Design: A two-armed, nonblinded, randomised control trial with repeated follow-ups, of N = 153 participants at baseline allocated to an intervention (n = 80) and control (n = 73) group.
Method: Inclusion criteria were the following: ≥65 years of age, living in ordinary housing, in need of assistance in two or more self-reported activities of daily living, having at least two hospital admissions or at least four visits in outpatient care 12 months prior to enrolment. Case managers (nurses and physiotherapists) provided an intervention of general case management, general information, specific information and continuity and safety. The intervention ranged over 12 months with one or more home visit(s) being conducted per month. An intention-to-treat analysis was applied for the primary outcomes of loneliness, depressive symptoms and life satisfaction, along with complete case and sensitivity analyses.
Results: During the trial period n = 12 died and n = 33 dropped out. No significant difference was found between the groups at baseline regarding sociodemographic characteristics, subjective health or primary outcomes. The intention-to-treat analysis did not result in any significant effects for the primary outcomes at any of the follow-ups (6 and 12 months). The complete case analysis resulted in a significant difference in favour of the intervention regarding loneliness (RR = 0.49, p = 0.028) and life satisfaction (ES = 0.41, p = 0.028) at 6 months and for depressive symptoms (ES = 0.47, p = 0.035) at 12 months.
Conclusions: The use of case management for frail older people did not result in clear favourable effects for the primary outcomes. However, the study indicates that case management may be beneficial in terms of these outcomes. Due to the complexity of the outcomes, an elaboration of the components and assessments is suggested.

Keywords: case management, community health services, depression, frail elderly, life satisfaction, loneliness, nursing, randomised controlled trial.

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Introduction

Poor psychological health among older people is widespread, albeit a neglected area, where providing social support is highlighted as an area in need of improvement (1, 2). Among older people loneliness is a prevalent phenomenon, internationally (3, 4) as well as nationally (5). Loneliness has serious consequences for cognition, emotion, behaviour and overall health if left unattended (6) where a reciprocal association between loneliness and depressive symptoms appears to be salient (4, 6). The importance of promoting and utilising psychological resources has been highlighted as fundamental for healthy ageing (7). However, frail older people, in particular, have complex medical and social needs and their overall care is characterised by fragmentation and weak accountability (8). Case management is one approach to face the challenge of delivering coordinated, and integrated care, which encompasses prevention as well as

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medical and social needs, including dealing with poor psychological health. To date, there are very few published randomised controlled trials (RCT) aiming to evaluate the effects of using case management for frail older people in regard to dealing with loneliness, depressive symptoms and life satisfaction.

Background

The core of case management comprises planning, facilitation, coordination, evaluation and advocating, based on an individual's comprehensive health needs (7, 9). In a systematic review by You et al. (10) (N = 15, n = 10 RCTs, n = 5 quasi-experimental trials), the available evidence showed that case management in community aged care can improve psychological health and well-being of the clients. Assessing these psychological aspects, including loneliness, are emphasised as an important part of case management (8, 11, 12) in order to achieve successful client outcomes (13). Moreover, when being frail, the importance of prevention and early intervention has been emphasised to counteract negative outcomes experienced by these individuals (14). Briefly, the term frailty can be seen as a state with multiple causes and contributors, resulting in an increased vulnerability for developing increased dependency and/or death (15) as well as an increased risk of institutionalisation and use of healthcare services (16).

Masi et al. (17) highlights the distinction between loneliness and social isolation, where loneliness is the social equivalent of physical pain, and seeking connections to feel safe, secure and content with life alleviates, whereas social isolation is an objective measure of social interactions and relationships. Thus, loneliness is a subjective and undesired experience involving a negative affect (4, 18). Moreover, the known reciprocal relationship between loneliness and depression (4, 6, 19) is apparent when older people themselves describe the experience of depression as being associated with loneliness, isolation and shielding (20). Symptoms of depression among older people differ from younger people where the former displays somatic symptoms, cognitive changes and loss of interest. This can be characterised by depressed mood, decreased energy, feelings of worthlessness and inability to enjoy pleasurable activities or events, among others (21). In regard to the fact that loneliness is associated with both physical and psychological adverse health outcomes (4), including lower life satisfaction (5, 22), and depressed mood (4, 5), elucidates the importance of recognition in clinical practice.

There is evidence that case managers benefit a client's perception of psychological support in terms of providing reassurance, feelings of security and social support (12). In addition, attributes such as self-efficacy, self-esteem, confidence, optimism, purpose in life and coping are of major importance for healthy ageing (7) and these attributes are reflected in the concept of life satisfaction as described by Neugarten et al. (23). Low self-esteem has been found to be associated with lower life satisfaction among older Europeans, along with being unsatisfied with social contacts and feeling hindered by health problems (24). Accordingly, the actual effect of case management for frail older people in regard to life satisfaction as well as loneliness is of further interest, but remains unclear due to the limited number of published experimental trials and, in particular, RCTs.

Frail older people living at home are currently at risk of receiving fragmented care with limited focus on psychological health as well as social support. Evaluation of the comprehensive approach, as provided in case management, with focus on loneliness, depressive symptoms and life satisfaction, would generate additional knowledge concerning the care and well-being of frail older people.

Aim

The aim of the study was to investigate the effects of a case management intervention to community-dwelling frail older people with functional dependency and repeated contacts with the healthcare services, focusing on loneliness, depressive symptoms and life satisfaction.

Method

Design

The study had a nonblinded, two-armed randomised controlled design (RCT) with repeated follow-ups. The study has been developed applying the Medical Research Council (MRC) framework for complex interventions (25–27) using a stepwise approach including development, feasibility/piloting, evaluation and implementation (25, 26). The development phase included a literature review (28). Thereafter, the intervention programme was developed and included a pilot study (29) and final modifications of the intervention. To date, there are three published experimental studies evaluating the effect of the case management intervention in relation to falls (30), in relation to healthcare utilisation (31) and in relation to cost utility (32).

Setting and sample

The study was conducted in a medium-sized municipality in the County of Skåne in Southern Sweden, with approximately 32 000 inhabitants. The municipality contains one town and rural areas. In total, 153 participants were enrolled in the study, with 80 participants

randomised to an intervention group, and 73 participants randomised to a control group (Fig. 1). The participants were consecutively recruited between October 2006 to April 2010 from three clinics at the local university hospital (n = 20), three primary healthcare centres in the municipality (n = 117), the home care organisation in the municipality (n = 13) or through self-referrals by contacting the research group (n = 3). Inclusion criteria were as follows: 65 years of age or older, living in ordinary housing in the municipality, being in need of assistance in two or more self-reported activities of daily living (ADL), having at least two hospital admissions or at least four visits in outpatient care 12 months prior to enrolment in the project. The participant was also able to communicate verbally in Swedish and had no severe cognitive impairment. To determine cognitive impairment, the Mini Mental State Examination (33) was used with a range between zero and 30 points, where a cut-off score of ≥25 points was considered as having no cognitive impairment.

Altogether, 1079 persons were assessed for eligibility. The participants were recruited by staff at the facilities who asked a potential participant if he or she agreed to be contacted by a team member in the research group. At the hospital, three nurses involved in the study managed the recruitment process. The majority of the participants (n = 862) were assessed for eligibility through a screening procedure performed on two occasions at two primary healthcare centres in the municipality (≥4 visits at the primary clinic during the previous year) and contacted by telephone or mail. When contacted by telephone, the potential participants were given verbal information and were assessed for eligibility by a member in the research group. When contacted by mail, potential participants were given written information about the study and asked to complete and return a prepaid form saying that they were interested in the study. If this was done, a research group member called up, providing further information, gained consent and assessed for eligibility. Finally, some participants were recruited by

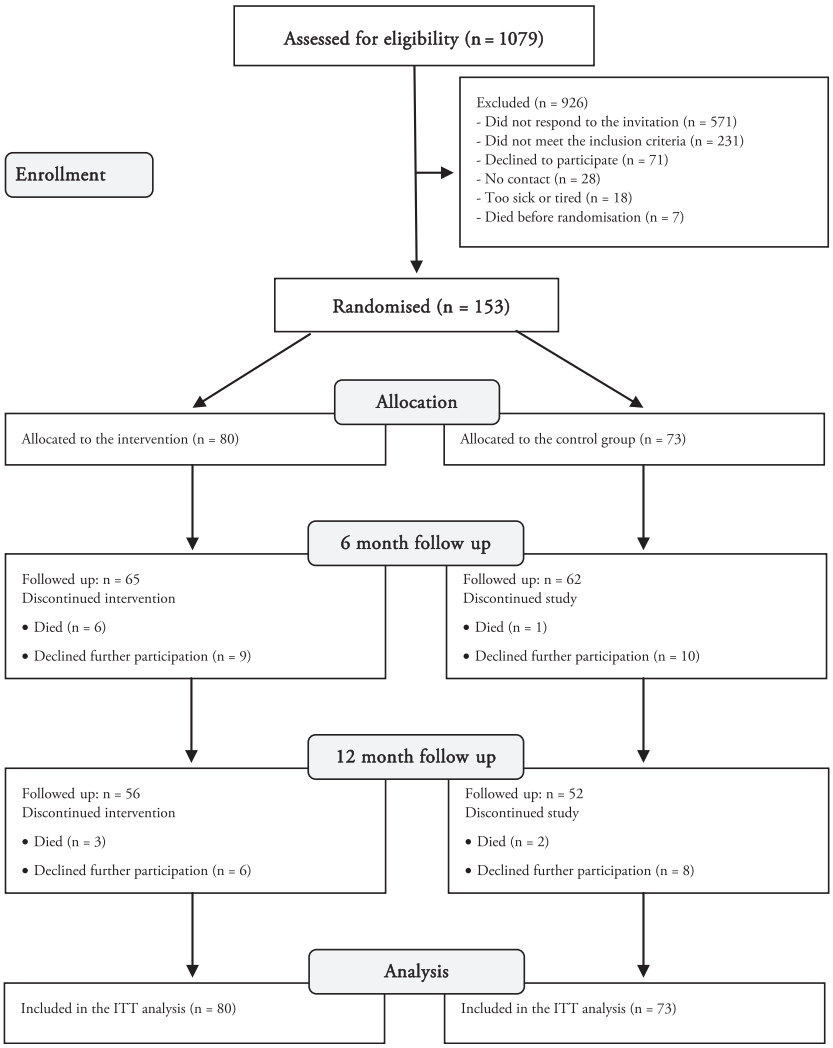

Figure 1 CONSORT flow diagram.

self-referral. Information leaflets regarding the study were provided at eligible settings, enabling individuals themselves to contact the project team. Reasons for not being recruited were as follows: did not respond to invitation (n = 571), did not meet the inclusion criteria (n = 231), declined to participate (n = 71), could not be reached (n = 28), were too sick or tired (n = 18) or had died before randomisation (n = 7) (Fig. 1).

The randomisation procedure, carried out by members of the research group, included sealed envelopes containing a note informing if the participant was allocated to the control or the intervention group. The possibility of being randomised to either group was equal, and the procedure was undertaken after inclusion and prior to baseline.

The case management intervention. The intervention was given over a 12-month period. The case managers represented two professions, nurses (RN) and physiotherapists (PT). All participants in the intervention group were given a case manager (CM) from each profession. It should be noted that in the piloting phase of the intervention, there was only a RN CM (29). The PT CM was introduced after the piloting phase. The two CMs (RN and PT) did either a monthly home visit together or separately (i.e. one monthly visit for each CM, respectively). Thus, home visit's occurred at least once a month for each CM or more frequently, if needed. The intervention comprised of four main components: general case management (I), general information (II), specific information (III) and continuity and safety (IV) (29, 34). General case management (I) included assessment of lifestyle, functional and cognitive status and nursing needs of the individual. A care plan was developed based on the assessment undertaken and included monitoring and evaluation. In addition, this component of case management also comprised care coordination, navigation in the healthcare system, advocating as well as encouraging social activities. This could mean guiding, assisting and supporting participants in their contact with different establishments in the healthcare system, including guiding towards an accurate level of care or accompany the participant to outpatient visits. General information (II) was provided regarding the healthcare system, as well as details concerning ageing and its consequences. Information regarding activities arranged by the municipality, such as social activities, was also given. Specific information (III) was comprised of information focusing on the participants' specific health problems and needs, including the use of medication and exercise, as well as psychosocial aspects. This could, for example, mean how and when to administer a certain medical product or give ideas and support of what to do if feeling lonely or isolated. In addition, an evaluation of the prescribed medications was made, and a physician connected to the project, also reviewed the prescribed medications for inaccuracies in both the intervention and control groups. Continuity and safety (IV) included availability and reachability. This meant that the CMs were reachable by telephone to participants during office hours for answering questions, assist in solving problems, as well as provide assistance in crisis situations.

The CMs intervened according to the four main components, although focus differed depending on the individual professionals' expertise. The RN CM focused on nursing care related to health, medications and psychosocial aspects. The Mini Data Set for Home Care (MD-HC) (35) was used by the RN CM as a regular part of the overall assessment and covers demographic characteristics, functional and cognitive status and nursing needs. The PT CM focused on fall prevention and physical functioning. In addition, the PT could include a social activity as a part of an exercise session and the RN used a similar approach where a social activity could be combined with a practical errand, such as stopping for coffee while going to the pharmacy (34). The interventions given to each of the participants were documented by the CMs, including diaries with personal reflections (29). It was also possible to contact a physician involved in the project if needed. All CMs communicated and collaborated regularly with the research group, including attending steering group meetings (29, 34). During the steering group meetings, the CMs presented specific participant cases that were brought up for discussion both from a problem-solving aspect and/or success aspect. On average, each RN CM made eleven visits and two phone calls throughout the 12-month intervention period to those participants who completed the intervention. Corresponding average for the PT CM was ten visits and one phone call (34).

Standard care. During the study, all participants were receiving standard care. This care was according to the Swedish *Health Medical Services Act*, encompassing health and medical care, and the *Social Services Act*, encompassing home care services. The care according to the two legal acts is provided by the municipality and the county council in terms of in- and outpatient care, and home care services. Home care services are based on a need assessment carried out by the municipality and can include meals-on-wheels, cleaning, shopping and assistance in personal activities such as showering. If medical specialised care is needed, the participants could receive home nursing and/or other assistance such as rehabilitation.

Data collection

Questionnaires were collected by means of structural interviews in the participant's home at baseline, and at 3-, 6-, 9- and 12-month intervals. The questionnaires

from baseline, 6- and 12-month intervals were used in this study and encompassed several assessments and questions from which primary and secondary outcomes were selected. The assessors were members of the project team who all had training in performing structural interviews as well as assessing the questionnaire.

Measurements

Three primary outcomes were chosen and analysed at baseline, 6 and 12 months for the purpose of evaluating the effects of the intervention in regard to loneliness, depressive symptoms and life satisfaction. For baseline characteristics of the sample, assessments covering sociodemographics and health aspects were chosen.

Primary outcomes. Loneliness was assessed by a single-item question regarding the prevalence of loneliness (at the time of the assessment): 'Do you feel lonely nowadays?' with three response alternatives: 1. Yes, I feel very lonely 2. Yes, I feel rather lonely 3. No, I don't feel lonely. A dichotomisation (0/1) of the response alternatives was made into not lonely (3 = 0) and lonely (1–2 = 1). The Geriatric Depression Scale-20 (GDS-20) comprising of 20 questions (yes/no) assessed depressive symptoms. The GDS-20 generates a score from zero to 20, where a cut-off score ≥6 indicates risk of depression and has been validated in a Swedish context (36). Levels of life satisfaction was obtained by using the Life Satisfaction Index-Z (LSIZ) (37) consisting of 13 items in statement form, including both negative and positive statements, on a three-point Likert scale (agree, don't know, disagree). The scores range from zero to 26, and a higher score indicated greater satisfaction. The LSIZ has been translated into Swedish, and the instrument is suitable for measuring general life satisfaction in older people (38).

Baseline measures. To describe the characteristics of the sample, single-item questions covering age, gender, civil status, educational level and use of municipal care was applied. In addition to this, the following assessments were made: level of dependence in personal activities in daily living (PADL) and instrumental activities in daily living (IADL) was obtained by a supplemented ADL staircase (39) based on Katz's ADL index (40), and the supplement constitutes four well-defined IADL (39). PADL refers to six activities: bathing, dressing, going to the toilet, transfer, continence, feeding, with IADL referring to four activities: cleaning, shopping, transportation and cooking. The instrument generated a score ranging from zero to ten based on the performance of each of the ten activities (can (0)/cannot (1)), where ≥1 indicates dependency in ADL. The EuroQol instrument (EQ-5D) (41), which assesses health-related quality of life, contains a visual analogue scale (VAS). The VAS ranges from zero (worst imaginable health state) to 100 (best imaginable health state), on which the participant was asked to score his or her current health status (41). This information was used as an indicator of the subjective health status among the participants. A single-item question for assessing depressive mood as a health complaint was drawn from a total of 32 different questions regarding common health complaints for older people, which were assessed by the presence and severity during the last 3 months, with four response alternatives (1. No; 2. Yes, little; 3. Yes, quite a lot; 4. Yes, very much). The original version of health complaints (42) has been revised by adding response alternatives and symptoms from a later study (43). The response alternatives for the item assessing depressed mood were dichotomised as 'no' = 0 and 'yes, little', 'yes, quite a lot' and 'yes, very much' = 1. Data on prescribed antidepressive medication (yes (1)/no (0)) were assessed using the Downton Fall Risk Index (44) and treated as a single item. Finally, a dichotomous single-item question was used covering whether the participant had a confidant or not (yes (0)/no (1)). The latter three items served as background data, primarily for the main outcomes of depressive symptoms (the items for depressed mood and prescribed antidepressive medication) and loneliness (having a confidant or not).

Statistical analysis

Intention-to-treat analysis. This study was performed according to the intention-to-treat principle (ITT), meaning that all participants were kept in the group to which they were assigned, or accounted for in the final analysis of treatment effects (45). The primary outcomes: loneliness, depressive symptoms and life satisfaction, were included in the ITT analysis. A complete case analysis was also performed for the primary outcomes. For the ITT analysis, missing outcome data pattern was analysed and plausible assumptions about the missing data were considered. Imputation method was chosen based on these assumptions (46). The last observed value replaced the missing value according to the last-observation-carried-forward (LOCF) method (47) applied, and when baseline data was missing, the subsequent value for the item replaced the baseline data. In those cases where no data were available at any time point on item level, the value of zero (0) replaced the missing value. This occurred in two cases for the loneliness variable and in seven cases at item level for the GDS-20 variable. To enhance the robustness of the ITT analysis, supplementary analyses were undertaken for the main outcomes at baseline and the follow-ups (46). For the item assessing loneliness, all missing values were imputed with (0) for a best-case scenario, and (1) for a worst-case scenario. For the GDS-20 and the LSIZ, a likelihood-based approach

and expectation maximisation (EM) (46, 48) were used. The supplementary analyses investigating the missing data from different approaches served as a sensitivity analysis of the results from the ITT analysis (44).

Statistical tests. For comparisons between the intervention (0) and control groups (1), the Student's *t*-test was used for normally distributed interval data and the Mann–Whitney *U*-test was used for interval data, which was not normally distributed. For nominal data, the chi-square test or the Fischer's exact probability test was used. One-Way repeated-measures ANOVA, for interval data, and Cochran's *Q*-test, for nominal data, were used for comparisons over time within the intervention and control groups. When significant values, Cohen's *d* for interval data was calculated and used to determine the effect size (ES), 0.20 was considered a small effect, 0.50 a medium effect and 0.80 a large effect (49). For nominal data, the relative risk (RR) was used as an indicator of ES. The differences (Δ) in ES for each of the primary outcomes were calculated between baseline and 6 months, and baseline and 12 months for the intervention and control groups, applying the values suggested by Cohen (49) or if RR, in percentage. For repeated measures, the p-value was adjusted according to the Bonferroni method and set to 0.017; for all other analyses, a p-value less or equal to 0.050 was considered as statistically significant. The software program IBM SPSS Statistics (versions 21, 22) was used for the statistical analyses.

Power analysis. To avoid type II errors, a power analysis was conducted *a priori* to determine the sample size of the study. Depressive symptoms, assessed by the GDS-20, and life satisfaction, assessed by the LSIZ, were considered. The α-level was set to 0.05 and power $(1 - \beta)$ to 0.80. A mean change of 1.5 points with a standard deviation (SD) of 3.4 points over 12 months was considered relevant for depressive symptoms. Corresponding mean change for life satisfaction was set to 2.5 points with a SD of 4.8 points. Based on these assumptions, a total of 59 (LSIZ) to 81 (GDS-20) participants were required in each group.

Rigour

The CONSORT 2010 statement (50) and the CONSORT extension for nonpharmacological trials (51) were used as guidance when reporting. The main study is trial registered on ClinicalTrials.gov, NCT01829594.

Ethical considerations

The study was designed and conducted in accordance with the ethical principles stated in the Declaration of Helsinki (52). Beauchamp and Childress' (53) four ethical principles: respect for autonomy, nonmaleficence, beneficence and justice, were used for additional ethical guidance.

Results

Participant flow and baseline characteristics

Of the 153 participants randomised, 108 participants remained at the 12-month follow-up (n = 12 died, n = 33 dropped out), leaving 56 participants in the intervention group and 52 participants in the control group (Fig. 1). At baseline, the age span in the study ranged from 66 to 94 years of age, with a mean (*M*) age of 82 (SD = 6.4) years. The women were in the majority (67% vs. 33%) (Table 1), but did not differ in age compared to the men ($M = 82$, SD = 5.7 vs. $M = 81$, SD = 6.7). No significant difference was found between the intervention and control groups regarding age, marital status, educational level, ADL and use of municipal care (Table 1). The majority (68%) of the participants lived in an apartment or condominium, compared to 32% who lived in a house.

When using the EQ-$5D_{VAS}$ to rate current health status at baseline, the mean score of the total sample was 60 (SD = 17.5) on a zero to 100-scale, with 40% of the total sample reporting depressed mood as a health complaint, and with 16% prescribed antidepressive medication (Table 1). No significant differences were found between the two groups in regard to health status, depressed mood as a health complaint, prescribed antidepressive medication or having a confidant (Table 1).

The prevalence of loneliness at baseline, in the total sample (complete cases), was 24% (Table 2). The corresponding mean score for the GDS-20 was 6.0 (SD = 3.4), and for the LSIZ 14.7 (SD = 5.1), respectively. No significant difference was found between the groups regarding the three primary outcomes at baseline (Table 2).

Complete case analysis

In the 6-month follow-up, the complete case analysis resulted in significant differences between the groups regarding both loneliness (RR = 0.49, p = 0.028) and life satisfaction (ES = 0.41, p = 0.028) (Table 2). At the 12-month follow-up, a medium-sized effect was found in favour of the intervention (ES = 0.47, p = 0.035) regarding depressive symptoms. In addition, the mean score for the intervention group was below cut-off ($M = 5.0$, SD = 3.48) for the GDS-20, whereas the mean score for the control group was above ($M = 6.7$, SD = 3.74) (Table 2).

Intention-to-treat analysis

After replacing the missing data and conducting the ITT analysis, no significant differences between the two

Table 1 Characteristics at baseline including a comparison between the intervention and control group

	Total sample n = 153	*Intervention n = 80*	*Control n = 73*	*p-value*
Age, *M* (±SD)	81.5 (6.4)	81.4 (5.9)	81.6 (6.8)	0.796[a]
Gender, n, %				0.732[b]
Female	102 (66.7)	52 (65.0)	50 (68.5)	
Male	51 (33.3)	28 (35.0)	23 (31.5)	
Civil status, %				0.387[b]
Married, partner, cohabitant	34.0	28.8	39.7	
Widowed	49.0	51.3	46.6	
Divorced	8.5	8.8	8.2	
Living apart, other	8.5	11.3	5.5	
Education, %				0.401[b]
Primary school	46.4	42.5	50.0	
Secondary school	11.8	11.0	12.5	
Vocational school	35.9	42.5	30.0	
Higher education	5.9	4.1	7.5	
ADL *Mdn* (*q*1–*q*3)	2.0 (1.0–3.0)[1]	2.0 (1.0–3.0)	2.0 (1.0–3.0)	0.788[c]
Municipal care, %				
IADL	36.4[2]	39.1	33.3	0.572[b]
PADL	23.6[3]	29.8	16.7	0.146[b]
Meals-on-Wheels, %	12.6[4]	6.9	5.7	0.905[b]
EQ-5D$_{vas}$ *M* (±SD)	60.3 (17.5)[5]	59.0 (19.1)	61.7 (15.7)	0.343[a]
Depressed mood*, %	39.9	40.0	39.7	0.972[b]
Antidepressive**, %	16.3	13.8	19.2	0.651[b]
Confidant, %	96.7[6]	94.9	98.6	0.369[d]

[a]Student's *t*-test; [b]Chi-square test; [c]Mann–Whitney *U*-test; [d]Fisher's exact test; *Reported as a health complaint; **Prescribed medication.
Missing: 1 : 1; 2 : 65; 3 : 64; 4 : 66; 5 : 3, 6 : 2.

Table 2 Complete case analysis of primary outcome variables at baseline, 6 and 12 month follow-ups including a comparison between intervention and control groups

	Total sample n = 153	*Intervention n = 80*	*Control n = 73*	*p-value*	*ES*	Δ *ES*
Loneliness, %						
Baseline	24.4[1]	26.1	22.7	0.692[a]		
6 months	23.3[2]	15.9	31.6	**0.028**[a]	0.49[c]	0.22[e]
12 months	28.8[3]	27.3	30.6	0.829[a]		0.03[e]
GDS-20[∫] *M* (±SD)						
Baseline	6.0[4] (3.44)	6.0 (3.68)	5.9 (3.13)	0.802[b]		
6 months	5.3[5] (2.91)	5.0 (3.01)	5.7 (2.77)	0.208[b]		0.05[f]
12 months	5.8[6] (3.67)	5.0 (3.48)	6.7 (3.74)	**0.035**[b]	0.47[d]	0.23[f]
LSIZ[∫∫] *M* (±SD)						
Baseline	14.7 (5.10)	14.9 (5.05)	14.4 (5.18)	0.493[b]		
6 months	15.3[7] (4.99)	16.3 (4.69)	14.3 (5.12)	**0.028**[b]	0.41[d]	0.27[f]
12 months	15.4[8] (5.35)	15.8 (5.16)	15.0 (5.57)	0.447[b]		0.06[f]

[a]Chi-square test; [b]Student's *t*-test; [c]Relative risk (RR); dCohen's *d*; [e]Δ RR between intervention and control groups at baseline and 6 months and baseline and 12 months; [f]Δ Cohen's *d* between intervention and control groups at baseline and 6 months and baseline and 12 months, respectively.
[∫]Geriatric Depression Scale-20; [∫∫]Life Satisfaction Index-Z.
Missing: 1 : 18; 2 : 33; 3 : 49; 4 : 27; 5 : 48; 6 : 64; 7 : 37; 8 : 48.

groups were found for any of the primary outcomes, neither at baseline nor at the two follow-ups at 6 and 12 months (Table 3; Figs 2–4). Repeated measures within the intervention and control groups, respectively, revealed no significant differences over time between baseline and follow-ups (6 and 12 months) regarding loneliness (p = 0.092 and p = 0.532), depressive symptoms (p = 0.398 and p = 0.186) or life satisfaction (p = 0.641 and p = 0.421). The worst- and best-case scenario for the item assessing loneliness as well as the EM

approach for the LSIZ and the GDS-20 did not result in any significant differences between the two groups at any time point (data not shown).

Discussion

Discussion of results

According to the ITT analysis, this study showed that the intervention did not have a favourable significant effect on loneliness. Although the intervention comprised aspects regarding psychosocial health, there was no standardised or explicit strategy when intervening against loneliness. Instead, it was individually tailored and this could be reflected in the lack of effectiveness. However, identifying the frail older person's own barriers for overcoming loneliness has been suggested as a strategy in previous research (54). Considering the trend for prevalence of loneliness over time in the intervention group, along with the significant effect of the complete case analysis, it appears that the intervention may have had an effect on loneliness at 6 months from baseline. This could indicate that the support in terms of alleviating loneliness provided by the CM was sufficient initially, but not over a longer period of time. The content of the case management intervention may cover some dimensions of loneliness related to social aspects, which resulted in an initial favourable effect, but the strategy failed to accomplish a sustainable effect. Sandberg et al. (55) found that the participants in the case management study experienced the CM as an important source of social support and enjoyed having someone to talk to. However, Masi et al. (17) suggests that due to the complexity of loneliness, social interventions targeting social support and social skills are not the most effective strategies in combating loneliness, but rather targeting 'maladaptive social cognition', for instance through cognitive behavioural therapy (CBT). In line with previous findings, further improvement of case management should include a more structured and evidence-based approach in assessing and intervening against loneliness specifically, although with respect to individual needs and preferences.

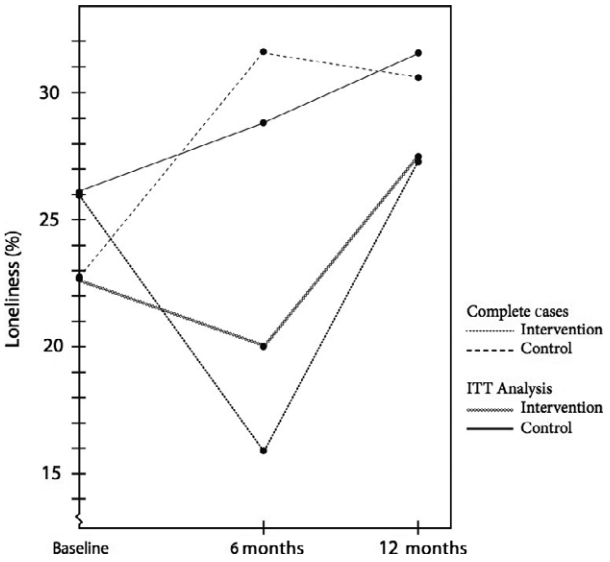

Figure 2 Prevalence of loneliness for the ITT and complete case analyses in the intervention and control groups, respectively.

Table 3 ITT analysis* of primary outcome variables at baseline, 6 and 12 month follow-ups including a comparison between intervention and control groups

	Total sample n = 153	*Intervention n = 80*	*Control n = 73*	*p-value*	Δ *ES*
Loneliness, %					
Baseline	26.1	26.3	26.0	0.975[a]	
6 months	24.2	20.0	28.8	0.206[a]	0.15[c]
12 months	29.4	27.5	31.5	0.587[a]	0.13[c]
GDS-20[∫] *M* (±SD)					
Baseline	6.2 (3.55)	6.3 (3.90)	6.2 (3.13)	0.862[b]	
6 months	6.0 (3.46)	5.9 (3.69)	6.1 (3.21)	0.643[b]	0.21[d]
12 months	6.2 (3.81)	5.9 (3.86)	6.6 (3.77)	0.314[b]	0.02[d]
LSIZ[∫∫] *M* (±SD)					
Baseline	14.7 (5.10)**	14.9 (5.05)**	14.4 (5.18)**	0.4936[b]	
6 months	14.8 (5.10)	15.2 (5.03)	14.4 (5.17)	0.326[b]	0.06[d]
12 months	14.9 (5.38)	14.9 (5.31)	14.8 (5.59)	0.906[b]	0.07[d]

[a]Chi-square test; [b]Student's *t*-test; [c]Δ R.R. between intervention and control groups at baseline and 6 months and baseline and 12 months; [d]Δ Cohen's d between intervention and control groups at baseline and 6 months and baseline and 12 months, respectively; *LOCF; **No missing values for LSIZ at baseline hence CC data.

[∫]Geriatric Depression Scale-20; [∫∫]Life Satisfaction Index-Z.

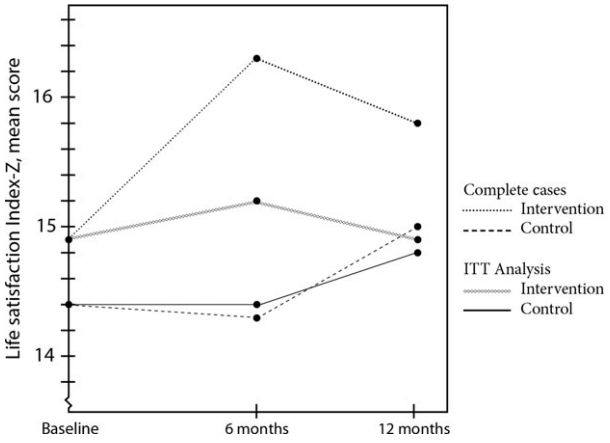

Figure 3 Mean score of the LSIZ for the ITT and complete case analyses in the intervention and control groups, respectively.

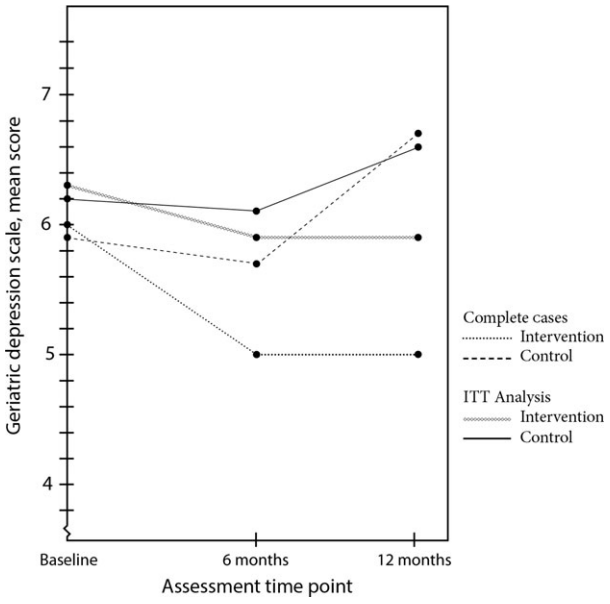

Figure 4 Mean score of the GDS-20 for the ITT and complete case analyses in the intervention and control groups, respectively.

A further important finding was that the participants in the total sample, as well as in both groups, were likely to be depressed, when applying the cut-off score for the GDS-20 (36). Although this is not equal to a clinical diagnosis, the finding shows that depressive symptoms are common among frail older people. Research conducted by Mezuk et al. (56) shows that there is a known reciprocal relationship between depression and frailty, and the need for providing appropriate support has been highlighted (1). The case management intervention did not result in a favourable significant effect on depressive symptoms. Nevertheless, when accounting for the trend of the GDS-20 scores over time, along with the complete case analyses, it indicates that the intervention group could have benefitted from the intervention. Integrated care, as well as collaborative interventions, has been shown as preferred and successful when caring for older people with depression (57). In addition, changing thoughts, behaviours, skills and associated feelings through CBT have shown to be effective in reducing depressive symptoms among older people (58). This is in line with suggested strategies in combating loneliness (17). Given the reciprocal relationship between loneliness and depression (4, 6, 19, 20), it would be of further interest to elaborate and investigate the possibilities of providing support beyond social dimensions. Nevertheless, early recognition of depressive symptoms has shown to be effective in preventing recurrent episodes of depression (21). Thus, the CM could play an important role in detecting those at risk, providing basic preventive or reductive strategies and when needed, advocating and for advanced treatment such as CBT.

The final primary outcome of this study was related to life satisfaction and can be seen as the opposite to depressive symptoms experienced by individuals since it refers to the positive aspect of the psychological well-being, including maintaining happy and optimistic (23). The mean scores of the LSIZ, in the total sample as well as in both groups, respectively, are in line with previous reported scores for similar samples in Sweden as well as in other European countries (59). However, among older (60+ years) Swedes in general, a mean score of 18 (SD = 4.8) has been reported (60) and supports that frail older people appear to have a lower life satisfaction compared to older people in general. Moreover, being less satisfied with life is associated by deficits in social contacts, feeling hindered by health problems and low self-esteem (24). The components of the intervention were intended to cover the mentioned factors as well as enhancing overall psychological well-being of individuals. Previous research on case management for frail older people has shown favourable effects in regard to aspects of life satisfaction such as satisfaction with psychological health (61). Nevertheless, there are difficulties in attempting to provide an intervention against psychological well-being due to stigma as well as referring to physical symptoms instead of psychological (57). Seemingly, it could be that the physical-oriented components of the intervention were more feasible for the CM delivering the intervention as well as for the older person himself or herself. Despite the absence of significant positive outcomes for case management in this study, there are indications that frail older people could benefit from the use of case management in terms of loneliness, symptoms of depression and life satisfaction. However, when aiming to target these complex phenomena, this study indicates that an elaboration comprising a focused and specific intervention strategy, with well-defined outcomes, could potentially be more beneficial for the frail older person.

This compared to a broader approach such as applied in the case management intervention. Nevertheless, this study indicates that the CMs and the services they provide have an important role in the caring process for frail older people living at home. By applying the core principles of case management, assessment, planning, facilitation, coordination, evaluation and advocating (9), loneliness and depressive symptoms could be relieved either by the CM or by referrals to primary care, including the advocating for evidence-based, state-of-the-art treatment and counselling. Moreover, this could also potentially result in increased life satisfaction for the frail older person. Given the vulnerable situation for those who are frail, and the importance of prevention in order to counteract disability (14), the potential influence of psychological well-being needs to be recognised as well as further investigated and evaluated.

Limitations

In this study, as well as in the main study, loneliness was conceptualised as a negative experience. When assessing loneliness in form of a single-item question, neither a definition nor a specific type of loneliness was articulated. It cannot be ruled out that the participants may have had a diverging conceptualisation, hence threatening construct validity. However, using a single-item question when assessing loneliness has the advantage of approaching direct feelings of loneliness (4). Also, in the questionnaire used in the main study various aspects of loneliness were assessed by single-item questions and it would be reasonable to assume that diverging conceptualisations were not frequently occurring among the participants.

The participants in the study were considered to be frail based on the inclusion criteria of functional dependency and repeated contacts with the healthcare services. Not using a well-established assessment for identifying frailty could threaten the external validity. However, there is no international standard or perfect frailty assessment tool (62). Nevertheless, there is a consensus regarding preferable screening assessments where the Clinical Frailty Scale (CFR) (63) has been recommended (15). In line with the CFR, the participants in the present study can be considered to be mildly or moderately frail, that is being need for help in IADLs or being in need for help in IADLs and some PADLs (15, 63). Although an assessment with the CFR was not performed, there is nevertheless support that the sample in fact was frail in various degrees.

In regard to internal validity, the random assignment itself improves and supports internal validity by enabling other conditions, apart from the intervention effects, to be experienced equally between the groups within the limits of chance (64). However, the attrition that occurred after participants were randomised, encompassing missing items in the questionnaire, as well as declining further participation, may affect the internal validity (64). During the study period, 29% (n = 45) of the participants dropped out due to several reasons, as described in the flow diagram (Fig. 1), although nearly one-third of the dropouts were inevitable due to death. In regard to the intervention and control groups, the attrition was fairly equally distributed. A previously published dropout analysis of the study sample showed no significant difference between the dropouts and the remaining sample in regard to age, gender, financial status, health complaints, functional dependency and depressive symptoms (31). Accordingly, there appears to be no treatment-correlated attrition of participants, which strengthens the internal validity (64). Based on the assumptions regarding the missing data in the study, it was considered to be missing at random (MAR); that is, the systematic difference can be traced or predicted within the complete data set but not directly due to the variables in which data were missing (48, 65). The ITT principle was applied to maintain the benefits of random assignment (64), and with the intention of reporting unbiased results (46, 65). The appliance of ITT and imputing missing values have implications for the statistical conclusion validity in terms of both threats and strengths. Applying LOCF as a method for imputing is common (46) but also criticised. However, the sensitivity analyses yielded no significant differences between the intervention and control groups, at any time point, supporting the validity of the chosen approach. Furthermore, when imputing missing data, the gained estimate of the treatment effect is often conservative (66, 67) or underestimated (68). Nevertheless, applying ITT when conducting a RCT is recommended as well as required according to the CONSORT statement (50). Given the potential threats and strengths for statistical conclusion validity as well as internal validity, it is suggested that the interpretation of the results from the ITT analysis in this study should be complemented with the results from the complete case analysis. Finally, according to the MRC complex intervention framework, identifying the active ingredient in the intervention is of interest (26). However, due to the flexibility within the intervention in the present study, identifying the active ingredient(s) may be difficult (69). It is therefore suggested that conducting a process evaluation would be beneficial to further understand the barriers and facilitators in the provided intervention (25, 26).

Conclusion

Case management for frail older people living at home did not result in significant favourable effects regarding the prevalence of loneliness, symptoms of depression and life satisfaction. However, when accounting for the ITT analysis, as well as the complete cases, there are indications that case management can benefit the frail older person in terms of these three outcomes. Due to the

complexity of the outcomes, in relation to experience, definition and assessment, an elaboration of the intervention is suggested along with further research in accordance with the MRC framework.

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Author contributions

Dr. Elin Taube involved in design of the study, data collection, statistical analysis, interpretation of data and drafting of the manuscript. Dr. Jimmie Kristensson and Dr. Patrik Midlöv contributed to design of the study, interpretation of data, contribution to the manuscript and critical revision. Dr. Ulf Jakobsson participated in design of the study, statistical analysis, interpretation of data, contribution to the manuscript and critical revision.

Ethical approval

The study was approved by the Regional Ethical Committee at Lund University, Sweden (LU 342/2006, LU 499/2008). Verbal and written informed consent was obtained from all the participants in the study.

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