

Effects of a comprehensive educational group intervention in older women with cognitive complaints: A randomized controlled trial

Citation for published version (APA):

Hoogenhout, E., De Groot, R., Van der Elst, W., & Jolles, J. (2012). Effects of a comprehensive educational group intervention in older women with cognitive complaints: A randomized controlled trial. *Aging & Mental Health*, 16(2), 135-144. <https://doi.org/10.1080/13607863.2011.598846>

DOI:

[10.1080/13607863.2011.598846](https://doi.org/10.1080/13607863.2011.598846)

Document status and date:

Published: 01/01/2012

Document Version:

Peer reviewed version

Document license:

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Please check the document version of this publication:

- A submitted manuscript is the version of the article upon submission and before peer-review. There can be important differences between the submitted version and the official published version of record. People interested in the research are advised to contact the author for the final version of the publication, or visit the DOI to the publisher's website.
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- The final published version features the final layout of the paper including the volume, issue and page numbers.

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EFFECTS OF A COMPREHENSIVE EDUCATIONAL GROUP INTERVENTION IN
OLDER WOMEN WITH COGNITIVE COMPLAINTS: A RANDOMIZED
CONTROLLED TRIAL

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Word count of text (excluding abstract, tables/figures, and reference list) : 3876

Abstract

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OBJECTIVE: The current study presents a new comprehensive educational group intervention that offers psycho-education about cognitive aging and contextual factors (i.e., negative age stereotypes, beliefs, health, and lifestyle), focuses on skills and compensatory behavior, and incorporates group discussion. Its effects were investigated in community-dwelling older women who report normal age-related cognitive complaints.

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METHODS: A randomized controlled trial with an experimental and waiting list control condition was carried out in a sample of 50 women aged 60-75 years. As the main problem of these individuals were *perceived* cognitive deficits without *actual* cognitive decrements, metacognition served as the primary outcome measure. Objective cognitive functioning and psychological wellbeing were secondary outcome measures. A double baseline and a follow-up assessment were carried out.

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RESULTS: Participants in the experimental condition reported significantly fewer negative emotional reactions towards cognitive functioning ($U = 164.500, p = .004$). The reported effect size ($\delta = -.473$) could be interpreted as large.

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CONCLUSIONS: This new comprehensive educational group intervention reduces negative emotional reactions towards cognitive functioning, which seems a prerequisite for improved subjective cognitive functioning and wellbeing. It can potentially contribute the wellbeing of an important and large group of older adults.

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Keywords: cognitive aging, subjective forgetfulness, metacognition, intervention, outcome

Introduction

One of the most common complaints of normal aging refers to cognitive changes. The prevalence of such cognitive complaints increases with age (Cargin, Collie, Masters, & Maruff, 2008; Jonker, Geerlings, & Schmand, 2000; Minett, Da Silva, Ortiz, & Bertolucci, 2008; Ponds, Commissaris, & Jolles, 1997). Such perceived cognitive problems are a source of worry and frustration (Commissaris, et al., 1993), and contribute to a lowered quality of life and decreases in wellbeing (Mol, Van Boxtel, Willems, Verhey, & Jolles, 2009). Although aging-related decrements in cognitive functions are largely inevitable, the association between cognitive complaints and actual cognitive decline is weak (Kliegel, Zimprich, & Eschen, 2005; Minett, Dean, Firbank, English, & O'Brien, 2005; Mol, Van Boxtel, Willems, & Jolles, 2006). Nevertheless, many people who consider themselves to be forgetful are worried that this may be a sign of a pathological condition such as a degenerative brain disease (e.g., Alzheimer dementia) (Commissaris, et al., 1993). They consequently appeal on specialized and costly healthcare services (e.g., memory clinics) (Comijs, Dik, Aartsen, Deeg, & Jonker, 2005; Verhey, et al., 2007). There is thus a major challenge to develop effective interventions for this target group.

A dominant view in cognitive aging research is that changes in memory reflect changes in the information-processing system, for example cognitive slowing (Salthouse, 1996) or problems in inhibitory functions (Craik & Bialystok, 2006; Van Hooren, Valentijn, Bosma, Ponds, Van Boxtel, et al., 2007). This might lead to an incomplete understanding and characterization of cognitive aging (Hess, 2005). For that reason, Hess (2005) argued for a broader consideration of cognitive aging from a life span perspective in which the adaptive nature of cognition as well as contextual factors (e.g., social context, negative stereotyping, personal goal setting, beliefs about aging, health and lifestyle) are taken into account. This

alternative perspective to cognitive aging is multidimensional and has several implications for the development of interventions for older adults with cognitive complaints or objective decrements in cognitive functions.

Interventions traditionally involved cognitive training, which brings about task and domain specific effects that hardly generalize to subjective cognitive functioning, wellbeing or everyday outcome (Ball, et al., 2002; Floyd & Scogin, 1997; Rebok, Carlson, & Langbaum, 2007; Verhaeghen, Marcoen, & Goossens, 1992; Willis, et al., 2006). It is stated that future intervention studies should find a way to increase awareness and knowledge, decrease negative beliefs, and decrease negative memory-related affect (Floyd & Scogin, 1997; Hohaus, 2007; Rebok, et al., 2007; Verhaeghen, et al., 1992). This may be achieved by developing interventions with a strong educational focus that promote a more realistic understanding of cognitive aging and relevant contextual factors (e.g., health, lifestyle, beliefs, metacognition), counteract stereotypes and provide compensatory techniques (Floyd & Scogin, 1997; Hess, 2005; Hohaus, 2007; Lachman, 1991; McDougall, 2009). There are several studies that investigate the effects of such multi-dimensional intervention approaches. These studies vary greatly in content, design and outcome (see for example (Hohaus, 2007; Lachman, Weaver, Bandura, Elliott, & Lewkowicz, 1992; Mohs, et al., 1998; Stuss, et al., 2007; Troyer, 2001; Valentijn, et al., 2005; Van Hooren, Valentijn, Bosma, Ponds, van Boxtel, et al., 2007; West, Bagwell, & Dark-Freudeman, 2008; Winocur, et al., 2007).

The current study evaluated the effectiveness of a new educational intervention program that has evolved from previous successful intervention studies by our research group (Commissaris, Verhey, & Jolles, 1996; Valentijn, et al., 2005; Van Hooren, Valentijn, Bosma, Ponds, van Boxtel, et al., 2007). The intervention has a strong educational component and fits the ideas of successful aging as defined by Baltes and Baltes (1990) in the model of selective optimization with compensation. It offers information about cognitive aging and the influence

of contextual factors (Hess, 2005). It extensively discusses the use of commonly applicable compensatory strategies (Bäckman & Dixon, 1992; Van Hooren, Valentijn, Bosma, Ponds, van Boxtel, et al., 2007). Furthermore, it incorporates group discussion (Flynn & Storandt, 1990; Valentijn, et al., 2005) about societal and personal beliefs, negative aging stereotypes (Hess, 2005), and pessimistic and maladaptive attributions (Commissaris, et al., 1993; Lachman & McArthur, 1986)^b.

A randomized controlled trial was carried out in a homogenous sample of older community-dwelling women with cognitive complaints that can be attributed to normal aging. A fundamental premise was that the main problem of this target group was an aging-related perceived cognitive decline that has limited predictive value for actual cognitive losses (Kliegel, et al., 2005; Mol, et al., 2006). As is stated by other researchers it is important to decrease, for example, negative feelings about cognitive functioning (Floyd & Scogin, 1997; Hohaus, 2007; Rebok, et al., 2007; Verhaeghen, et al., 1992). For that reason, the primary aim of the present study was to investigate whether the intervention effectively did so, thus metacognitive functioning served as a primary outcome measure. Secondly, in order to investigate whether these effects generalized to other domains, the effects on objective cognitive performance and psychological wellbeing were examined.

Methods

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Participants

Participants were recruited through announcements on a regional radio station, and through advertisements in local and regional weeklies. In order to create a homogenous study sample there were age (i.e., between 60 and 75 years) and sex (i.e., being woman) restrictions

^b Note that a more extensive overview of traditional cognitive interventions and multidimensional approaches, as well as a detailed description of the intervention's background, content and process evaluation are provided in Hoogenhout, De Groot, and Jolles (2011).

120 to inclusion. Previous research revealed that people in this age range generally report many
cognitive complaints that can be ascribed to normal cognitive aging (Ponds, et al., 1997). The
creation of single sex intervention groups has a clinical advantage, because relevant topics
and reported everyday cognitive problems differ for men and women (Van Hooren, Valentijn,
Bosma, Ponds, van Boxtel, et al., 2007).

125 Other inclusion criteria were: reporting age-related cognitive complaints and/or
concerns about becoming demented (as measured with a semi-structured interview), and good
comprehension of the Dutch language. Exclusion criteria were a score of 24 or lower on the
Mini-Mental State Examination (Folstein, Folstein, & McHugh, 1975), the occurrence of any
neurological disorder (e.g., stroke or dementia), or any (previous) psychiatric disorder (e.g.,
130 major depressive disorder or schizophrenia).

Procedure

The study was designed as a randomized controlled trial. After screening by telephone,
eligible persons were sent an information letter about the intervention study. People who were
135 willing to participate were randomly assigned to an experimental or waiting list control
condition. Randomization and allocation were done by computer. All participants then
received an individual intake interview. A double baseline cognitive assessment was carried
out with about one week in between. Additionally, all participants filled in several
questionnaires at baseline. In this way, all variables were measured once (i.e., self-report
140 questionnaires) or twice (i.e., cognitive assessment) at baseline. Within one or two weeks
after the baseline assessment, participants in the experimental condition started the four-week
intervention. Participants in the control condition were placed on a waiting list for four weeks.
Both the cognitive tests and questionnaires were administered to all participants
approximately seven weeks after the start of the study (see Figure 1). Participants'

145 characteristics are listed in Table 2 in the Results section. Assessors were not involved in the
interventions. Afterwards, participants in the waiting list control condition were offered the
intervention program. All participants were assessed in the Maastricht University Medical
Centre. Interventions were offered at a research location at Maastricht University. The
medical ethics committee of the Maastricht University Medical Centre approved the study and
150 all participants gave their informed consent.

The intervention program

The content of the intervention program is listed in Table 1. The 4-week intervention
consisted of eight 1.5-hour group sessions, with six to nine participants per group. The
155 intervention was offered in a structured manner and within a standard time frame. Each
session started with the evaluation and recapitulation of the content of the previous session (\pm
10 minutes). In addition, homework assignments were discussed and questions were answered
(\pm 10 minutes). Afterwards, several themes and topics were introduced one by one in short
blocks, which was supported by a PowerPoint slideshow with handouts (\pm 40 minutes in
160 total). After each block, beliefs and attitudes with respect to the theme were shared and
discussed in the group (\pm 20 minutes in total). Each session ended with a summary of the
session's themes, answering questions and a short preview of the homework assignments (\pm
10 minutes).

165 >>Insert Table 1 about here<<

Measures

Metacognitive functioning. The primary outcome measure was metacognitive functioning as assessed with the Maastricht Metacognition Inventory (MMI), a newly developed instrument that has several advantages over existing questionnaires (e.g., its focus on metacognition instead of metamemory). The MMI is a multidimensional questionnaire which consists of four scales, i.e., Ability, Affect, Control, and Strategy. The Ability scale consists of 16 items that measured everyday cognitive failures (e.g., difficulty to carry out two simultaneous tasks). The Affect scale contains 11 items that measured emotional reactions towards everyday cognitive failures (e.g., get annoyed when forgetting something). The Control scale contains 5 items that measured complaints about the sense of control over cognitive functioning (e.g., be unable to preserve oneself from cognitive decline). The Strategy scale contains 11 items that measured the use of compensation strategies (e.g., relate information to something that is known well). All items were rated on a 5-point Likert scale, ranging from 1 (= strongly disagree), to 5 (= strongly agree). Higher scores indicated more everyday cognitive failures, more emotional reactions towards cognitive failures, more complaints about the sense of control over cognitive functioning, or the use of more compensation strategies, respectively.

The psychometric properties of the MMI were shown to be good in a large sample of $N = 552$ cognitively healthy older adults (aged 50-95 years). A confirmatory factor analysis provided support for the construct validity of the MMI (i.e., the obtained factor structure was highly consistent with the *a priori* expected 4-factor model; RMSEA = .052, 90% CI = .050 - .055, $p = .071$), and the internal consistency of the items of the four MMI scales was high (Cronbach's *alpha* coefficients ranged between .74 and .91) (Hoogenhout, Van der Elst, De Groot, & Jolles, under revision).

Objective cognitive functioning and psychological wellbeing. Objective cognitive functioning and psychological wellbeing were measured with composite scores in order to increase power and improve ecological validity. For a detailed description of the calculation method see Van der Elst, Van Boxtel, Van Breukelen, and Jolles (2008). In order to control for procedural learning effects in cognitive assessment, only data from the second baseline assessment were used.

The Memory Quotient (MQ) was based on the Visual Verbal Learning Test (VVLT) (Van der Elst, Van Boxtel, Van Breukelen, & Jolles, 2005), an adaptation to the Rey Verbal Learning Test, that measured the ability to learn new information and the ability to retrieve information from memory. The total score of the first three immediate recall trials (VVLT 1-3) and the delayed recall score (VVLT delayed) were used to construct the MQ. Parallel versions were used for each assessment. Higher MQ scores indicate better memory functioning.

The Executive functioning and Speed Quotient (ESQ) is a composite cognitive measure that was based on the Stroop Colour Word Test (SCWT), the Concept Shifting Test (CST), and the Letter Digit Substitution Test (LDST) test scores. The SCWT was a measure of interference control and speed of information processing (Van der Elst, Van Boxtel, Van Breukelen, & Jolles, 2006c). SCWT time (i.e., time needed to complete the third card) and SCWT errors (i.e., number of errors on the third trial) were used to construct the ESQ (Van der Elst, et al., 2008). The CST is adapted from the Trail Making Test and consisted of several subtasks. In each subtask, 16 small circles were grouped in a larger circle. Participants were asked to cross out the items as fast as possible in numerical order (part A), alphabetical order (part B), or alternating (part C). The time to complete each subtest was recorded (Van der Elst, Van Boxtel, Van Breukelen, & Jolles, 2006a). Shifting score ($CST_{shifting} = CST_c - [CST_a + CST_b]/2$) and the number of errors made in part C (CST errors) were used to

construct the ESQ (Van der Elst, et al., 2008). The LDST measured general speed of information processing. Participants were asked to replace randomized letters with appropriate numbers indicated by a key, as quickly and accurately as possible (Van der Elst, Van Boxtel, Van Breukelen, & Jolles, 2006b). The number of correct substitutions made in 60 seconds (LDST60) was used to construct the ESQ (Van der Elst, et al., 2008). Higher ESQ scores indicate better executive functioning and higher speed.

The Psychological Wellbeing Quotient (PWQ) was calculated using the Centre of Epidemiologic Studies Depression scale (CES-D, total score inverted; Bouma, Ranchor, Sanderman, & Van Sonderen, 1995), the Neurovegetative Complaints Questionnaire (NCQ, two scale scores inverted; Hoogenhout, Van der Elst, De Groot, Van Boxtel, & Jolles, 2010) and the mental composite score of the Medical Outcome Study 36-item Short-Form Health Survey (SF-36; Ware, Kosinski, & Keller, 1994). Higher PWQ scores indicate better psychological wellbeing. The CES-D contained 20 statements concerning depressive symptoms (e.g., feeling lonely) in the week prior to test administration. Participants had to indicate symptom frequency on a 4-point scale, ranging from ‘seldom or never’ (= 0) to ‘usually or all the time’ (= 3). Higher scores indicated more depressive symptoms (Bouma, et al., 1995). The NCQ consisted of two subscales (with 11 and 9 items) that measured neurovegetative/somatic complaints (e.g., heart palpitations) or reactive/emotional complaints (e.g., irritability). Participants had to indicate the frequency of occurrence on a 4-point scale ranging from 1 (= no, never) to 4 (= yes, often). Higher scores indicated more complaints (Hoogenhout, et al., 2010). The SF-36 contained 36 items that can be divided in nine subscales. From a selection of these subscales, a composite for mental wellbeing can be calculated (Sanderman, Arrindell, Ranchor, Eysenck, & Eysenck, 1995; Ware, et al., 1994). Higher SF-36 mental composite scores indicated better mental wellbeing.

Other measures. In order to investigate participants' characteristics several background variables were assessed. Educational level was measured on an 8-point ordinal scale, ranging from primary education to university education. Furthermore, information about marital status was collected (married/living together or unmarried). Two subscales of the self-reported Eysenck Personality Inventory (EPQ; Sanderman, et al., 1995) were administered to measure neuroticism (e.g., being emotional unstable), and extraversion (e.g., being talkative). These subscales consisted of 22 and 19 dichotomous items (i.e., 1 = yes, 0 = no). Higher scores indicated more neuroticism or extraversion.

Statistical Analyses

Differences in baseline characteristics between the groups (i.e., experimental and control) were investigated in order to verify whether randomisation was successful. A One-way Analysis of Variance (ANOVA) was performed for age, and Mann Whitney U tests for educational level, EPQ neuroticism and extraversion and MMSE scores. A Chi-square test was used to analyze marital status. Baseline differences in outcome measures were investigated by performing ANOVA's on baseline scores.

Change scores (i.e., change score = posttest score – pretest score) were calculated for all outcome measures. In case of violation of the normality assumption (as checked with Shapiro Wilks tests), non-parametric Mann Whitney U tests were carried out on relevant change scores. Otherwise, parametric ANOVAs were carried out (with the relevant change score as dependent variable) to investigate differences between the groups. In addition, Cliff's δ scores were calculated, which are effect size estimates that are less sensitive to violations of the normality assumption. Like Cohen's d effect estimates (Cohen, 1988), Cliff's δ scores could be interpreted as small ($\delta = .147$), medium ($\delta = .330$), or large ($\delta = .474$) effects

(Kromrey & Hogarty, 1998; Leech & Onwuegbuzie, 2002; Romano, Kromrey, Coraggio, & Skowronek, 2006).

Consistent with the rules for clinical trials (Altman, et al., 2001), analyses were based
270 on the principle of intention-to-treat. Full application of the intention-to-treat principle was,
however, impossible because complete outcome data for participants who dropped-out before
the end of the study were not available and could consequently not be analysed. A
significance level of .01 was used to adjust for multiple comparisons. All analyses were
carried out using PASW 18.0 for Macintosh.

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Results

Recruitment of participants

Results of recruitment and randomization are given in Figure 1. A total of 108 people
280 were screened for participation. Forty-eight of them were excluded: 28 did not meet inclusion
criteria and 20 declined to participate after receiving more information about the intervention
and the experiment. The remaining 60 participants were randomly assigned to either the
experimental or the waiting-list control group. The experimental group started with 30
participants. Six of them decided to end their participation prematurely, due to logistic
285 problems (n = 3), health-related problems (n = 2) or lack of interest (n = 1). The waiting list
control group started with 30 participants, four of whom terminated their participation before
the end of the study. The main reasons were health-related problems (n = 3) and lack of
interest (n = 1). This resulted in a total sample of fifty people, twenty-four of whom were
experimental and twenty-six were waiting list control participants.

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>>Insert Figure 1 about here<<

Baseline characteristics

There were no group differences in demographic characteristics, EPQ-scores, and MMSE scores at baseline (see Table 2). Participants who dropped out and participants who
295 accomplished the study only differed in EPQ extraversion scores ($U = 34.000, p = .028$), with those who dropped out reporting higher Extraversion levels.

>>Insert Table 2 about here<<

300 Intervention effects

Results are presented in Table 3. Shapiro Wilks tests for normality indicated that the normality assumption was violated for the MMI-Affect, MMI-Control, MQ, and ESQ change scores. Consequently, non-parametric Mann Whitney U tests instead of parametric ANOVAs were carried out on these variables. No significant differences in scores at baseline were
305 established between the experimental and waiting-list control group for any of the outcome measures (see Table 3). Analyses on the primary outcome measure (i.e., the MMI scale scores) revealed a significant difference in Affect scores ($U = 164.500, p = .004$). Relative to their baseline functioning, participants in the experimental group reported less emotional reactions towards cognitive functioning than participants in the control condition immediately
310 after intervention. The reported effect size ($\delta = -.473$) could be interpreted as large (Leech & Onwuegbuzie, 2002; Romano, et al., 2006). There were no significant differences between the groups in Ability ($F(1, 49) = .577, p = .451$), Control ($U = 302.500, p = .852$), and Strategy ($F(1, 49) = 1.713, p = .197$) scores. Moreover, no significant differences were established in objective cognitive functioning as measured with the Memory Quotient ($U = 229.000, p =$
315 $.161$) and the Executive functioning and Speed Quotient ($U = 274.000, p = .616$), or

psychological wellbeing as measured with the Psychological Wellbeing Quotient ($F(1, 49) = .069, p = .794$).

>>Insert Table 3 about here<<

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Discussion

The current study evaluated a new comprehensive educational group intervention in healthy older women with age-related cognitive complaints. A detailed description of its background and content as well as the results of a process evaluation are provided by Hoogenhout, De Groot, and Jolles (2011). Results indicated that participants in the experimental condition reported fewer negative emotional reactions towards cognitive functioning as compared to participants in the waiting list control group immediately after intervention. Effect size estimates (Cliff's $\delta = -.473$) suggested that this effect could be interpreted as large (Leech & Onwuegbuzie, 2002; Romano, et al., 2006). The intervention thus improved an important aspect of metacognition. No statistical significant differences were found for other aspects of metacognition (i.e., everyday cognitive failures, complaints about a low sense of control, and the use of compensation strategies), objective cognitive functioning or psychological wellbeing. It is worth noticing that we included participants who were high performing on cognitive measures (i.e., we included a relatively healthy sample) (Van der Elst, et al., 2005, 2006a, 2006b, 2006c). Nevertheless, reported Cliff's δ effect size estimates (see Table 3) point to medium effects in the expected direction on, for example, objective memory performance ($\delta = .237$). With better power obtained by a larger study population this effect will probably show statistical significance (Cohen, 1988).

There are several strengths of our study. First, we carried out a randomized controlled trial with an experimental group and a waiting list control group, which allows us to obtain

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relatively robust results and draw reliable conclusions (Altman, et al., 2001). Note however that our study has several limitations that are common in psychosocial intervention research (e.g., the lack of a third non-specific placebo condition, and lack of blindness of participants and trainers). Second, we included a homogeneous and carefully selected study sample to
345 minimize the influence of inter-individual variability in functioning on group comparisons. It is worth to investigate whether positive effects extend to other target groups, like men, adults aged above 75 years, or individuals with mild cognitive impairment. Third, a common problem in intervention research is a lack of instruments that are sensitive enough to detect relatively small changes in functioning due to intervention (Floyd & Scogin, 1997; Hohaus,
350 2007; Mohs, et al., 1998; Verhaeghen, et al., 1992), especially if healthy older adults are included who generally report minor problems and show relatively small cognitive loss (Hess, 2005; Hohaus, 2007). We therefore tried to optimize outcome measurement by using sensitive and ecologically valid cognitive composite scores (Van der Elst, et al., 2008), and by developing a new metacognition instrument (i.e., the MMI) (Hoogenhout, et al., under
355 revision) that had several advantages over existing instruments (e.g., its focus on metacognition instead of metamemory alone). To further optimize the outcome measurements and ecological validity, future studies might include alternative measures of everyday cognitive functioning (e.g., timed instrumental activities of daily living; Owsley, Sloane, McGwin, & Ball, 2002)

360 Our results were obtained immediately after intervention. In order to investigate whether the effects remain over a considerable amount of time, further research is needed. It has been argued that in the course of time other aspects of subjective cognitive functioning, objective cognitive functioning and/or psychological wellbeing are likely to change secondary to changes in metacognition or subjective cognitive functioning (McDougall, 2009; Van
365 Hooren, Valentijn, Bosma, Ponds, van Boxtel, et al., 2007). Previous studies suggested that

future intervention studies in healthy older adults with cognitive complaints should focus on decreasing negative beliefs and reducing negative memory-related affect. This goal was only marginally achieved by traditional interventions that primarily focus on cognitive training (Floyd & Scogin, 1997; Hess, 2005; Hohaus, 2007; Rebok, et al., 2007). Our findings further support evidence that multidimensional interventions with a strong educational focus are effective in doing so. In our opinion, the only program that significantly shared characteristics and content with our intervention was described by Hohaus (2007). She compared an educational intervention that incorporated principles of selection optimization and compensation to an active control condition in twenty versus twenty community-dwelling older adults (aged 56 to 84 years). Significant differences between the groups were reported on measures of objective and subjective memory performance. Contrary to Hohaus (2007), we were able to carry out a randomized controlled trial. Furthermore, we performed a double baseline assessment to be sure that potential significant differences in cognitive outcome were not caused by procedural learning effects.

We consider the intervention a potentially valuable contribution to a relevant health issue in older adults. It may offer an opportunity for relatively low-level treatment and can potentially contribute to the wellbeing of an important and large group of older adults.

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Acknowledgements

555 There are no conflicts of interest affecting this manuscript.

The authors thank Esther Steins and Climmy van den Nieuwenhof for their help in implementing the intervention. The assistance of Sil Aarts, Annette Joosten and Annelies Wouters in collecting the data has been highly appreciated.