

TREATMENT

Brief Alcohol Intervention by Newly Trained Workers Versus Leaflets: Comparison of Effect in Older Heavy Drinkers Identified in a Population Health Examination Survey: A Randomized Controlled Trial

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Abstract — **Aims:** To test if a brief motivational intervention (BMI) in a non-treatment seeking population of heavy drinkers results in a reduced alcohol intake. **Methods:** Screening of 12,364 participants in a Danish health examination survey led to 1026 heavy drinkers of whom 772 were included and randomized to a BMI group ($n=391$) or a control group ($n=381$) receiving two leaflets about alcohol. Follow-up took place after 6 and 12 months including 670 and 616 participants respectively. The outcome measure was self-reported weekly alcohol consumption. Data were analysed according to the intention-to-treat principle. We used the Motivational Interviewing Treatment Integrity 3.0 code (MITI) as a quality control of the interventions delivered. **Results:** The intervention effect of the BMI was -1.0 drinks/week, but the effect was not significant. The MITI analysis showed that the quality of the BMI delivered was sub-optimal, as only one of four aspects was above the recommended level for beginning proficiency. **Conclusion:** We found no effect of a BMI in reducing alcohol consumption. The generalizability of the study is questionable, as individuals with the lowest level of education, low income and unmarried individuals are under-represented.

INTRODUCTION

Long-term heavy alcohol intake is associated with numerous somatic and psychiatric conditions (Schuckit, 2009). Additionally, heavy alcohol use causes social harm such as having a negative impact on the drinker's family (Casswell *et al.*, 2011). Other externalities of heavy alcohol use include increased levels of violence and traffic injury (Room *et al.*, 2005). On the population level, the majority of alcohol-related harm is not due to drinkers with alcohol dependence, but a result of a much larger group of drinkers whose consumption causes an increased risk of alcohol-related harm (Poikolainen *et al.*, 2007). It has been estimated that ~20% of the adult Danish population are heavy drinkers (Gottlieb Hansen *et al.*, 2011). Hence, the need is obvious for an effective preventive approach to reduce heavy drinking. For this, brief interventions have been advocated (Whitlock *et al.*, 2004; Kaner, 2010). Brief interventions can be defined as consultations of short duration (one to four sessions) undertaken by healthcare personnel, with the aim of motivating high-risk drinkers to moderate their alcohol consumption, rather than promote total abstinence. Brief interventions commonly target people who are not dependent and not seeking treatment, which seems to be important as only few of those who are heavy drinkers acknowledge themselves as having a problem with alcohol (McLellan, 2007; Saitz, 2010).

Systematic reviews of controlled trials show that clinically significant reductions in alcohol consumption can follow from opportunistic delivered brief interventions. Evidence is strongest for primary care populations (Beich *et al.*, 2003; Ballesteros *et al.*, 2004a; Bertholet *et al.*, 2005; Kaner *et al.*, 2007), but efficacy has also been shown in health screening programmes in general populations (Kristenson *et al.*, 1983; Nilssen, 1991, 2004) and student settings (Carey *et al.*, 2007). Evidence for emergency departments and hospital settings is mixed (Field *et al.*, 2010) or inconclusive (McQueen *et al.*, 2009). Brief interventions do not represent a single form of activity, but can be seen as a family of interventions,

and sometimes brief interventions adopt the principles and techniques of motivational interviewing (MI), and are hence termed brief motivational interventions (BMI) (Rollnick *et al.*, 1992; Heather, 2010; Rollnick *et al.*, 2010). Including a motivational component in brief interventions has shown to be an efficacious strategy for reducing alcohol consumption (Vasilaki *et al.*, 2006; Carey *et al.*, 2007). However, an important question concerns the optimal duration of a BMI and especially the exploration of how brief BMI can be and still be effective (Nilsen, 2010). This is underlined by an average intervention duration of more than 1 h in a meta-analysis of BMI (Vasilaki *et al.*, 2006), and by an average intervention duration of more than 20 min in the latest meta-analysis of brief interventions in primary care populations (Kaner *et al.*, 2007). Exploring how the content and setting of delivery of brief interventions have an impact on efficacy is important, both because the evidence for the added benefits of the motivational component is unclear and because the evidence base for very brief forms of BMI (<15 min) outside student settings is unclear (Heather, 2010). Furthermore, in Denmark, BMI studies targeting heavy drinkers in settings outside primary health-care remain untested.

The aim of the present study was to investigate the efficacy of an opportunistic BMI (~10 min) in conjunction with a telephone booster session (~5 min), in the context of a Danish Health Examination Survey (DANHES) (Eriksen *et al.*, 2011). The booster session was included because it could serve as a prompt to maintain behaviour change efforts. Previous studies have shown that this approach can help maintain and enhance effects of interventions (Botvin *et al.*, 1995). Our primary goal was to determine whether a BMI, resulted in lowering of alcohol use in a non-treatment seeking population of heavy drinkers, compared with subjects in a control group with a minimal intervention. As secondary aims, we also wished to determine if any gender-specific effects of the BMI could be found, especially because ambiguity remains when it comes to differential effectiveness between genders. Two meta-analyses found

that brief interventions were equally effective in men and women (Moyer *et al.*, 2002b; Ballesteros *et al.*, 2004b), whereas Kaner *et al.* (2007) found no significant reduction in alcohol consumption for women.

METHODS

Setting

The DANHES was carried out by the National Institute of Public Health, University of Southern Denmark in 13 municipalities in 2007/2008. The DANHES consisted of an internet-based questionnaire and a health examination. The present study was initiated after the beginning of the DANHES, and hence it was only possible to be implemented in 9 of the 13 municipalities. A random sample of the inhabitants was invited to participate in a health examination ($n = 121,103$). The sample was drawn from the adult Danish population (18 years or older) using the Danish Civil Registration System, which contains information on sex, age, address, citizenship and marital status for each individual (each Dane has a unique personal identification number). A total of 12,364 individuals participated in the health examination, resulting in a participation rate of 10% (Eriksen *et al.*, 2011).

Participants

Recruitment for the study began January 2008 and ended October 2008. Follow-up started June 2008 and ended in December 2009. Participants in DANHES completed an internet-based questionnaire containing questions on socio-demography, self-reported health status, living conditions and health behaviour including alcohol consumption. The baseline questionnaire was completed at the respondent's home. In seven out of nine municipalities the questionnaire was supplemented with a short readiness for health behaviour change questionnaire (weight, diet, smoking, alcohol), which was added after a preliminary evaluation of the DANHES baseline questionnaire. The alcohol questions were beverage-specific (beer, wine, fortified wine, spirits) and asked about consumption each day in a typical week. Additionally, the Alcohol Use Disorder Identification Test questions 3–10 were included (Babor *et al.*, 2001). Persons with a weekly alcohol consumption above the recommended maximum drinking limits, as given by The Danish National Board of Health (14 drinks = 168 g of alcohol for women, 21 drinks = 252 g for men) were eligible for the study. Dependent drinkers could be included in the study. One standard drink corresponds to 12 g of pure alcohol (Morch *et al.*, 2005). Heavy drinking was defined as 168/252 g of alcohol/week or more for women and men, respectively. Binge drinking was defined as drinking five or more drinks on a single occasion both for men and women. Prior to intervention, the participants had been attending a health examination, which took place in premises provided in the nine municipalities and consisted of an examination of blood pressure and resting heart rate, height, body weight and fat percentage, waist-hip ratio, blood samples (for examination of plasma levels of cholesterol, triglyceride, C-reactive protein and haemoglobin A1c), bone mineral density, pulmonary function, muscle strength, lower extremity function and aerobic fitness (Eriksen *et al.*, 2011). Afterwards,

participants were informed about the results of the health examination, and then finally presented for the BMI study. The participants were told they were being invited for the intervention study because of their alcohol use. On the whole, findings of the health examination were not discussed at the BMI.

Interventions

The BMI had a duration of ~10 min and consisted of a conversation based on the principles of MI, i.e. empathic, respectful and collaborative approach, designed to elicit motivation to change behaviour by asking open-ended question (summarized as the spirit of MI) (Rollnick *et al.*, 2010), two pamphlets about alcohol (The Danish National Board of Health, 2007a,b), a sheet with information about local alcohol treatment and a brief telephone booster session 4 weeks later. The purpose of the booster session was to maintain the participant's motivation to change drinking habits. The interventionists had been instructed to carry out the call in the spirit of MI, only as a reminder and not as a control measure, and were instructed that the duration of the booster session should be no more than 5 min.

The interventionists (mean age 36 years) consisted of three nurses and two MSc Public Health candidates, one psychologist candidate and two sociologists. Only the nurses had previous clinical experience. They had received 2 days of training (which is in line with Rollnick *et al.* who note that the training of practitioners in BMI should take no more than 12–15 h) (Rollnick *et al.*, 1992), one day in the spirit of MI and BMI elements by use of demonstration and role-play and one day in general information about alcohol. The interventionists also participated in a midway evaluation, where feedback was given by an expert on two audiotaped BMI. They had been instructed to ask three pre-defined open questions ('What do you know about the association between heavy drinking and health?', 'What are you already doing to restrain your drinking?' and 'What can you do more?') and to use scale questions [assessing importance of changing drinking and assessing confidence to change drinking habits (Rollnick, 1998)] during the intervention.

The control group received the same two leaflets about alcohol and the same sheet with information about local alcohol treatment. A pure control group, with no intervention, was not included for ethical reasons.

To document whether the staff carried out the intervention as planned, adherence with the protocol was assessed by analysing 39 BMI, which had been selected by the interventionists and recorded in full length. This was done using the MI Treatment Integrity 3.0 code (MITI) (Moyers *et al.*, 2007). MITI was chosen because it is a good tool for measuring entry-level competence in MI and has been shown to be an adequate measure of treatment integrity for MI (Pierson *et al.*, 2007). MITI rates interviewer behaviours by scoring of five global variables and by counting the frequency of seven behaviour counts. Five summary measures are derived from this tool and comparison is made with recommended standards based upon expert opinion (Table 2) (Moyers *et al.*, 2007). From MITI, we used the following summary measures: global spirit rating (summarizes the extent to which the interviewer has a collaborative style, evokes the use of personal reasons for change and supports their

Table 1. Baseline characteristics of participants randomized to BMI or control group in The Danish Health Examination Survey 2008

Characteristics	BMI	Control
Men		
<i>n</i> (%)	191 (49)	204 (54)
Age (years) ^a	60 (50–65)	59 (51–65)
Alcohol intake drinks/week ^b	31.1 (10.0)	32.6 (12.5)
Binge drinking, <i>n</i> (%) ^c	80 (42)	97 (48)
Education level, years <i>n</i> (%)		
<10	9 (29)	22 (71)
10–12	47 (57)	36 (43)
13–14	41 (54)	35 (46)
15+	71 (45)	86 (55)
Employed, <i>n</i> (%)	94 (47)	106 (53)
Smoking, <i>n</i> (%)		
Daily	16 (53)	14 (47)
Heavy ^d	21 (53)	19 (48)
Married or cohabitation, <i>n</i> (%)	132 (69)	143 (70)
Motivated to reduce alcohol use, <i>n</i> (%) ^e		
Yes	19 (13)	26 (17)
Yes, maybe	45 (31)	36 (24)
No	41 (28)	34 (23)
Women		
<i>n</i> (%)	200 (51)	177 (46)
Age (years) ^a	58 (48–64)	56 (49–64)
Alcohol intake drinks/week ^b	19.9 (5.8)	21.3 (7.7)
Binge drinking, <i>n</i> (%) ^c	37 (19)	46 (26)
Education level, years <i>n</i> (%)		
<10	22 (65)	12 (35)
10–12	34 (44)	44 (56)
13–14	44 (51)	43 (49)
15+	85 (56)	67 (44)
Employed, <i>n</i> (%)	96 (51)	91 (49)
Smoking, <i>n</i> (%)		
Daily	9 (53)	8 (47)
Heavy ^d	19 (61)	12 (39)
Married or cohabitation, <i>n</i> (%)	140 (70)	128 (72)
Motivated to reduce alcohol use, <i>n</i> (%) ^e		
Yes	20 (13)	25 (19)
Yes, maybe	35 (23)	45 (33)
No	50 (33)	36 (27)

SD, standard deviation; IQR, interquartile range.

^aMedian (IQR).

^bNumber of standard drinks in a typical week. Mean (SD).

^cDrinking five or more drinks per occasion at least once a week.

^dDefined as more than 15 cigarettes a day.

^eNumbers do not sum to 100% due to missing data.

autonomy), percent MI adherent (summarizes the extent to which the interviewer's verbal behaviours are consistent or inconsistent with an MI approach), and percent open questions, as the interventionists had been trained only in these dimensions of MI. Two of the authors, who had attended a one-day course in the use of MITI, independently double coded the 39 BMI which had been recorded.

Outcome measure

Results from previous meta-analyses made us aim for a mean between-group difference of 3–4 standard drinks (~40 g of alcohol) decrease per week in usual consumption (Bertholet *et al.*, 2005; Kaner *et al.*, 2007). Outcome measure was based on self-reported drinking and included beverage-specific (beer, wine, fortified wine, spirits) alcohol questions and asked about consumption each day in a typical week. Follow-up at 6 and 12 month was conducted using an internet-based questionnaire that participants accessed using a link provided in an e-mail. Follow-up was furthermore

supplemented by a letter containing the questionnaire, if the participants did not respond to the e-mail.

Power estimates

Based on the literature, reasonable reductions in the two groups are: BMI (25%), control group (10%) (Babor *et al.*, 1994; Moyer and Finney, 2002a). With a power of 80% probability of detecting a 25 vs 10% difference as statistically significant at the 5% level, approximately 100 participants would be needed for each group (Altman, 1990). Experiences from previous trials show that loss to follow-up must be expected to be around 25% (Kaner *et al.*, 2007). We expected that ~14% of the participants in DANHES were heavy drinkers (Ekholm *et al.*, 2006). Assuming that 60% accepted participation and 75% were followed up, this would give us a population of 720 persons, hence ensuring sufficient power.

Randomization

Eligible persons were informed orally and in writing about the study. After accepting and signing a written consent, they drew and opened a sealed opaque envelope from a mixed box that included equal numbers of envelopes containing a letter with either 'intervention group' or 'control group'. The box had been prepared beforehand and sorted randomly by the person responsible for the study. Simple randomization was performed by the sealed envelope method. Participants were enrolled into either BMI or control group by the responsible staff member. Blinding was not feasible, either for staff or for participants.

Statistical analysis

The primary and secondary analyses are based on the intention-to-treat principle (ITT) and concern the mean difference in changes in alcohol consumption between the BMI and control group. Analyses were carried out using Stata version 11.2 (StataCorp, USA). Quantitative variables were described by the mean and standard deviation (SD), by the median and its interquartile range or by its 95% confidence interval (95% CI). In all tests, $P < 0.05$ was chosen as the level of significance. A logistic regression model, with participation in follow-up as the dependent variable, was used to examine loss to follow-up. To examine changes over time and to account for the multiple time measurements, data were analysed by using a multilevel mixed model, using the *xtmixed* procedure. The model examined fixed effects for alcohol consumption, group, sex and follow-up assessment and included a random intercept to account for clustering within participant and a random slope that allows correlations between repeated measures to change over time (Finucane *et al.*, 2007). The fixed effect of most interest was the intervention effects of the BMI which indicates the difference between intervention group and control group in change over time of alcohol consumption.

To take attrition into account, we used multiple imputation to address missing data for participants who did not complete the 6- or 12-month follow-up. Multiple imputation allows for the uncertainty about the missing data by creating several different plausible imputed data sets and appropriately combining results obtained from each of them (we generated 20 data sets), which will often provide a more reliable

approach than complete-case analysis in the presence of missing data (Sterne *et al.*, 2009). For this we used the *mi impute mvn* procedure, which uses multivariate normal regression for continuous data and assumes arbitrary missingness (Lee and Carlin, 2010). As sensitivity analyses, we also report results from: (a) an ITT analysis assuming that non-responders have no change in their alcohol consumption (last observation carried forward) and (b) an analysis of all available results without imputation of missing data (completers only analysis).

In testing agreement between the two coders, who analysed the BMI, inter-rater reliability was estimated using the intraclass correlation coefficient (ICC). ICC assesses rating reliability by comparing the variability of different ratings of the same subject to the total variation across all ratings and all subjects. The following categorization system for evaluating ICCs was used: below 0.4 = poor, 0.4–0.59 = fair, 0.6–0.74 = good and 0.75–1.00 = excellent (Moyers *et al.*, 2005).

RESULTS

Participant flow

Of the 12,364 persons screened, 1026 were heavy drinkers (8.3%). Of these, 214 refused participation (21%), 19 were overlooked by the staff (2%) and 21 did not show up for the health examination (2%). In total, 772 persons accepted participation (75%) and were randomly assigned into a BMI ($n=391$) or control group ($n=381$). The 6-month follow-up was completed by 670 persons (87% of enrolled participants) and the 12-month follow-up was completed by 616 persons (80%) (Fig. 1). A total of 366 out of 391 persons received the telephone booster session (94%). On average, the BMI had a duration of 11 min. The duration of the telephone booster session was not recorded.

Baseline data

Men consumed a mean of 32 drinks/week and women 21 drinks/week. During the previous year, 45% of the men had been binge drinking once a week or more often, and among women the corresponding figure was 22%. At baseline, 251 persons (43%) answered 'yes' or 'yes, maybe' to the question: 'Do you want to cut down on your drinking?', 161 answered 'no' (28%) and 170 did not respond (29%), (only 582 persons received this question, because only seven of the nine municipalities received the 'readiness for health behaviour change questionnaire'). Median age was 59 years, 51% were men, 40% had more than 15 years of education, 50% were employed and 70% were married or cohabiting. Among participants, 6% were daily smokers and 9% were heavy smokers (more than 15 cigarettes a day). There were no significant differences between randomized groups for any baseline characteristic (Table 1).

MITI analysis and adherence to protocol

To examine adherence to protocol, MITI summary scores as found by the two coders, were compared with recommended standard for beginning proficiency. For the global spirit ratings, mean scores were respectively 3.6 (SD 0.7) and 3.8 (SD 0.5). The ratio of MI adherent to MI non-adherent utterances, were respectively 69% (SD 43) and 50% (SD 51). The ratio of open questions to open and closed questions,

were respectively 53% (SD 22) and 48% (SD 23). The ratio of reflections to questions were respectively 0.8 (SD 0.5) and 0.6 (SD 0.4). The MITI analysis showed that the mean global spirit ratings were above the recommended standard for beginning proficiency. Only according to coder one, was the ratio of open questions to open and closed questions above the recommended standard for beginning proficiency. Mean scores for the ratio of MI adherent to MI non-adherent utterances fell below this standard. The ratio of reflections to questions were below recommended standards, but it should be noted that the interventionists did not specifically receive training in this aspect of MI. ICC values for inter-rater agreement were in areas of fair to good (Table 2).

With regard to the three open questions, only in 21% of the tapes analysed, were the questions correctly phrased, i.e. as open questions. However 44% of the interventionists who did not phrase the questions as open, did ask about the same themes as in the open questions, but phrased as closed questions. As regards to the scale questions, 87% used these questions correctly.

Loss to follow-up analysis

Participants lost to follow-up ($n=103$ at 6 months and $n=156$ at 12 months, 17% of the sample) were compared with those who participated in the follow-up and did not differ in terms of baseline characteristics. The odds ratio (OR) of being in the BMI group compared with the control group was 0.8 (95% CI: 0.4–1.3), OR of being male was 0.9 (95% CI: 0.4–2.0), OR of being more than 45 years, was 0.7 (95% CI: 0.3–1.4), compared with being less than 45 years. OR of having more than 15 years of education was 1.1 (95% CI: 0.6–1.8), compared with less than 15 years of education. OR of being a smoker was 1.0 (95% CI: 0.5–2.0), compared with never or former smokers. OR of living with a partner or being married was 1.3 (95% CI: 0.7–2.4), compared with being single. OR of consuming more than 30 drinks/week was 1.3 (95% CI: 0.7–2.6), compared with consuming less than 30 drinks/week.

Outcomes

Table 3 presents the intervention effects of the BMI, which are expressed as the difference between the intervention group and control group in change over time of alcohol consumption (number of drinks/week), with and without imputation for missing values. The primary analysis using multiple imputation showed that the difference in number of drinks/week was 1.0 in favour of the BMI, but the difference was not significant (95% CI: –2.15 to 0.23). The two sensitivity analyses produced similar results. The difference between baseline and 6-month follow-up for the control group was –7.2 drinks/week and significant (95% CI: –8.06 to –6.36). Corresponding figures for 12-month follow-up were –7.3 (95% CI: –8.17 to –6.32). The two sensitivity analyses produced similar results (Table 3).

Alcohol consumption by gender and group, at baseline, 6- and 12-month follow-up, are shown in Figs. 2 and 3. Consumption among women decreased from a mean baseline level of 20.6–15.0 drinks/week for the control group (95% CI: 13.5–16.5) and 14.1 drinks/week for the BMI (95% CI: 12.9–15.2) after 6 months. Consumption among men decreased from a mean baseline level of 31.8–24.0 drinks/week for the

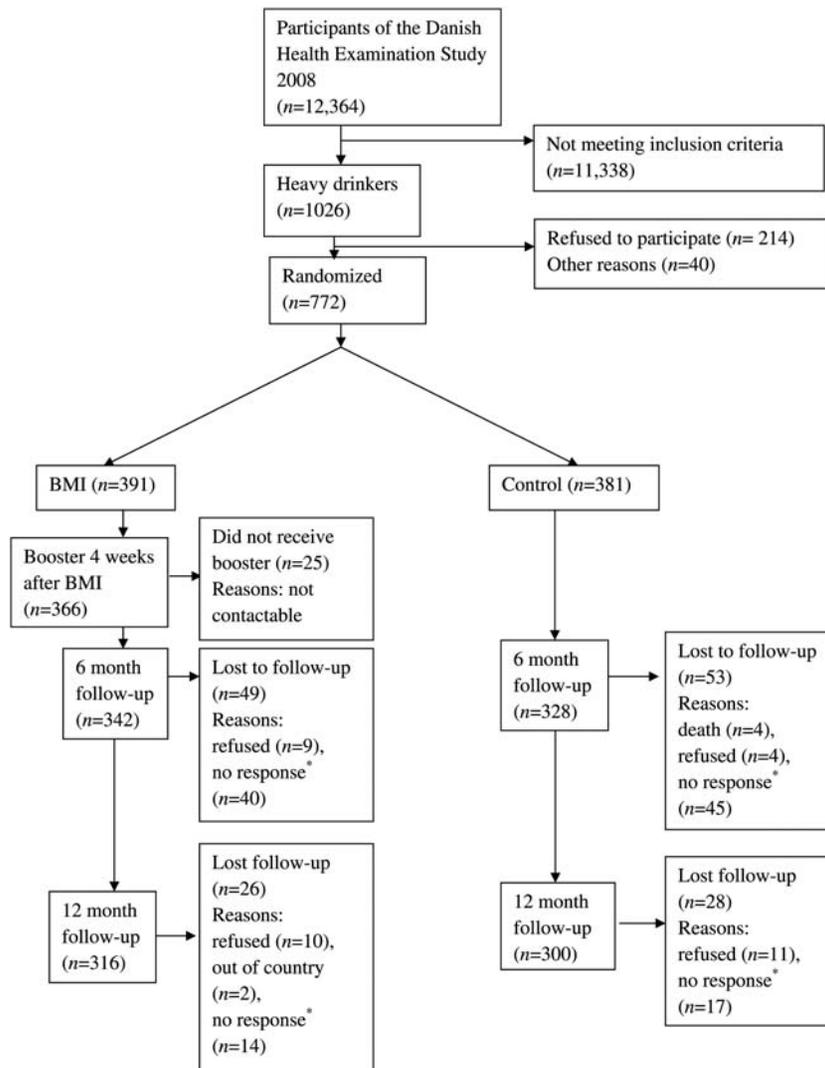


Fig. 1. Participant flowchart. *After two mails and two letters and a telephone call; BMI, brief motivational intervention.

Table 2. Overview of MITI, study mean scores and inter-rater reliability

Global ratings ^a	Summary measures	Recommended standard ^b	Study mean scores (SD)		
			Coder 1	Coder 2	ICC
Evocation					
Collaboration	Global spirit rating ^c	Average of 3.5	3.6 (0.7)	3.8 (0.5)	0.43
Autonomy/Support					
Direction					
Empathy					
Behaviour Counts					
Giving information					
MI adherent	% MI adherent ^d	90%	69% (43)	50% (51)	0.66
MI non-adherent					
Closed questions	% Open questions ^e	50%	53% (22)	48% (23)	0.69
Open questions					
Simple reflections	Reflection/questions ratio	1	0.8 (0.5)	0.6 (0.4)	0.62
Complex reflections	% Complex reflections ^f	40%	—	—	—

SD, standard deviation; MI, motivational interviewing; ICC, intraclass correlation coefficient;

MITI, Motivational Interviewing Treatment Integrity 3.0 code.

^aAre rated on a 5-point Likert-type scale ranging from 1 (low) to 5 (high).

^bRecommended standard for beginning proficiency.

^cComprises the average of evocation, collaboration, autonomy/support.

^dRatio of MI adherent to MI adherent and MI non-adherent statements.

^eRatio of open questions to open and closed questions.

^fRatio of complex reflections to simple and complex reflections.

Table 3. Intervention effects on drinks/week based on random intercept and slope models with and without imputation for missing values

	With multiple imputation for missing values ^a		Without multiple imputation for missing values (completers only) ^b		With simple imputation (last observation carried forward) ^c	
	Drinks/week (95% CI)	P-value	Drinks/week (95% CI)	P-value	Drinks/week (95% CI)	P-value
Intervention effects of the BMI	-1.0 (-2.15, 0.23)	0.114	-1.1 (-2.36, 0.10)	0.071	-1.2 (-2.43, 0.06)	0.061
Difference between baseline and follow-up for control group						
6 months	-7.2 (-8.06, -6.36)	<0.00	-7.3 (-8.08, -6.53)	<0.00	-6.4 (-7.06, -5.69)	<0.00
12 months	-7.2 (-8.17, -6.32)	<0.00	-7.5 (-8.40, -6.59)	<0.00	-6.9 (-7.70, -6.07)	<0.00

BMI, brief motivational intervention. Drinks/week, Number of standard drinks in a typical week. One Danish standard drink corresponds to 12 g of ethanol.

^aBased on 20 imputed data sets.

^bBased on 670 persons after 6 months and 616 persons after 12 months.

^cBased on 772 persons after 6 and 12 months.

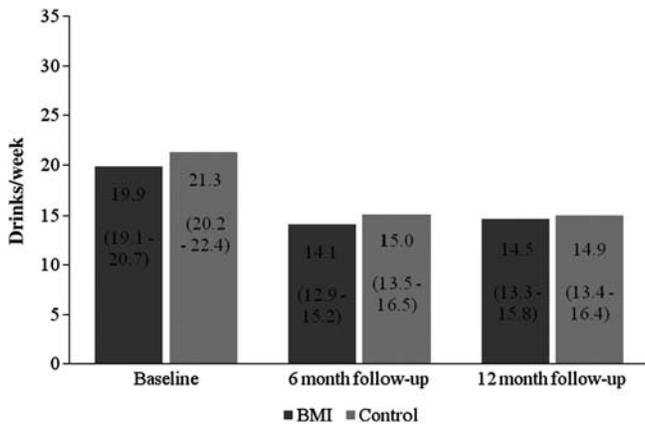


Fig. 2. Alcohol consumption at baseline and 6- and 12-month follow-up for women. Number of standard drinks in a typical week. One Danish standard drink corresponds to 12 g of ethanol. Mean (95% CI). Based on multiple imputation. BMI, brief motivational intervention.

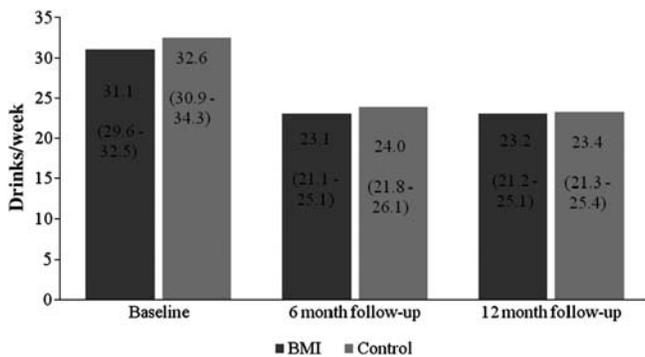


Fig. 3. Alcohol consumption at baseline, 6- and 12-month follow-up for men. Number of standard drinks in a typical week. One Danish standard drink corresponds to 12 g of ethanol. Mean (95% CI). Based on multiple imputation. BMI, brief motivational intervention.

control group (95% CI: 21.8–26.1) and 23.1 drinks/week for the BMI (95% CI: 21.1–25.1) after 6 months. Corresponding figures for 12-month follow-up were almost similar (Figs. 2 and 3).

DISCUSSION

In this randomized controlled trial, our aim was to investigate the efficacy of a BMI in conjunction with a 5 min telephone

booster session, in an attempt to find out how ‘stripped-down’ a minimal BMI could be composed and still demonstrate efficacy. We found no evidence that a BMI, as conducted by our interventionists, was effective. No significant difference was found between the BMI and simple information on alcohol intake and alcohol-related problems by means of two pamphlets. From baseline to 6- and 12-month follow-up, alcohol consumption declined significantly in both the BMI—and control group with approximately seven drinks per week.

Various factors may explain why the BMI did not have the anticipated effect: Participating in a health examination may have motivated participants to change their health behaviour and may have contributed to decreased alcohol consumption in both groups, however, fewer than 50% were motivated to change alcohol use (that is, of the subsample of 582 persons who were given questions about motivation). The non-blinded nature of the study, the fact that the leaflets in the control group were a minimal intervention, and assessment effects (intervention effects of the research procedures) could explain part of the reduction in the control group (Kypri *et al.*, 2007b). A majority of other studies have also reported significant reductions in control groups. These reductions may also be related to regression to the mean, social desirability bias and historical changes in alcohol consumption (Kypri, 2007a; Bernstein *et al.*, 2010).

A different partial explanation for the failure to show an advantage to BMI might be that we did not exclude dependent drinkers, which was the case in many other studies of brief interventions for alcohol.

Was the short duration of the BMI (11 min on average), insufficient in reducing alcohol consumption? Unfortunately our study does not permit to conclude on this, due to the lack of a pure control group. But even though the difference in alcohol consumption, we observed between the intervention and control group cannot be regarded as relevant in a public health setting, the reductions in the control group merit further exploration. Instead of only looking upon this reduction as a result of assessment effects and hence an adverse event to be avoided, it is possible to regard the assessment procedure (and the leaflets) as an ultra brief intervention in itself (McCambridge, 2009). One could speculate, that it was not the leaflets in itself that contributed to the reductions in the control group, but the fact the assessment procedure included a personal approach. A future challenge is to isolate and identify what aspects of the assessment procedures ‘... are the most potent and make them the centerpiece of a basic intervention that is truly brief’ (Saitz *et al.*,

2006). In this way an important research challenge can be approached: to explore how brief, brief interventions can be and still be effective (Nilsen, 2010). This is relevant, especially because, the average duration of a brief intervention was more than 20 min in the latest meta-analysis on brief interventions (Kaner *et al.*, 2007), and because research indicates that longer and shorter interventions achieve similar outcomes. As an example Wutzke *et al.* found that 5 min of simple advice was as effective as 60 min of advice and counselling (Wutzke *et al.*, 2002). Furthermore a meta-analysis of very brief (maximum duration of 15 min) single-session personalized-feedback interventions without therapeutic guidance found effect sizes similar to meta-analyses of face-to-face brief interventions (Riper *et al.*, 2009).

We used the MITI to document whether the interventionists actually did adhere to the style prescribed. This is important as research has shown that the use of MI non-adherent utterances in BMI are related to poorer drinking outcomes (Gaume *et al.*, 2009). The MITI analysis showed that the delivery of a BMI based on the principles of MI was sub-optimal, as only the global spirit rating was above the recommended level for beginning proficiency. The interventionists made use of fewer open rather than closed questions and fewer MI adherent rather than non-adherent utterances were used. With regard to the three open questions addressed by the intervention protocol, adherence was not impressive, but the majority of the interventionists used the scale questions correctly. When interpreting these results, it must be borne in mind that the interventionists only had received one day of training in MI and we can conclude that exploring the full potential of a BMI would have required more than one day of training.

Measuring outcome using self-reports of alcohol consumption has demonstrated reasonable levels of accuracy, but is also subject to some uncertainty and especially the tendency of respondents to underreport their drinking (social desirability bias) have been mentioned in the literature (Del Boca and Darkes, 2003; Kypri, 2007a). A limitation of this study concerns generalizability, which is questionable, because of the under-representation of individuals with the lowest level of education, low income and unmarried individuals in our population. Furthermore the study sample had a median age of 59 years. Few brief alcohol interventions have focused on older adults and evidence for this group is limited, albeit effectiveness has been shown (Fleming *et al.*, 1999; Moore *et al.*, 2011). Interest in this population is 2-fold, both because different risks are associated with heavy drinking due to age-related physiological changes and medication use; and because it has been found that older adults are less likely to experience harm from drinking over 'weekly limits' than younger (White *et al.*, 2002). This common knowledge, that alcohol in moderation may have overall health benefits, could negatively have affected our populations receptivity to a BMI, due to a low level of concern about their alcohol use.

Generalizability is a general problem of much brief intervention research dealing with populations which are not representative of the population of heavy drinkers (Edwards and Rollnick, 1997; Kypri, 2007a). This was confirmed by our results, which showed that in the DANHES population, 8.3% were heavy drinkers, compared with a 20% prevalence estimated for the Danish population (Gottlieb Hansen *et al.*, 2011).

In this rigorously conducted trial, we succeeded in implementing a BMI in a general population-based sample of heavy drinkers. The short duration of the BMI makes it a realistic candidate for use in primary health care and other settings. Important caveats in this study, which could explain the null findings, are the lack of a pure control group, the sub-optimal quality of the interventions delivered and the nature of the study population and setting, making it necessary to exercise caution in generalizing findings to other populations.

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