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Addressing the Boozing Booming Culture among ACT Women: Combining Innovative Technology with an Awareness Raising Campaign

Evaluation of the 'Ripple' intervention: Results of a Randomised Controlled Trial among middle-aged women in the ACT

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Executive Summary

Middle-aged women's drinking has become an area of increasing concern in Australia. A digital intervention was developed to assist Australian women aged 40-65 in reducing their drinking. The intervention tracked participants' drinking over time and provided them with information, resources and feedback to help reduce drinking. The trial was supported by a targeted awareness campaign and successfully launched on March 30th, 2021, where it was tested on a randomised controlled trial of women in the target age group living in the ACT. This report details the intervention, the sample and the effectiveness of the intervention across a range of primary and secondary outcomes. Data highlights intervention effects on the primary outcome, alcohol use, and indicates improvement in various secondary outcomes. However, high rates of attrition affect the generalisability of the findings. The follow-up survey was likely impacted by the most recent developments associated with COVID-19. As both primary and secondary outcomes indicate intervention effects in a highly under-targeted population, namely middle-aged women, a retesting in an RCT with a larger sample and circumstances less impacted by COVID-19 is suggested.

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Trial Background

Middle-aged Women and Alcohol in Australia

Historically men have consumed alcohol more often and in higher quantities than women (Wilsnack, Wilsnack, Kristjanson, Vogeltanz-Holm, & Gmel, 2009), but recent evidence has shown that rates of alcohol use have been converging among men and women (Slade et al., 2016). In Australia, this is particularly notable in middle-aged and older women, where rates of risky single occasion drinking, measured as five or more standard drinks on one a single occasion, in women aged 50-59 increased from 9.8% to 15.8% from 2001 to 2013, and in women aged 60-69 from 4.3% to 7.3% (Livingston, Callinan, Dietze, Stanesby, & Kuntsche, 2018).

Adult women's drinking has also been in the media spotlight due to social media trends relating to 'wine moms' (Fetters, 2020) and women using wine to cope with the stresses of motherhood (Seaver, 2020). This development is concerning because, compared to men, women are more susceptible to the long-term negative health effects of alcohol, including cardiovascular disease, cancer and diabetes (Erol & Karpyak, 2015). Women are also more likely to develop alcohol-use disorders from lower levels of consumption than men and are more vulnerable to the neurotoxic effects of alcohol (Erol & Karpyak, 2015). Thus, there is a need to understand and assist middle-aged women in reducing their alcohol use.

To address this issue, we aimed to develop an innovative online brief intervention to reduce alcohol use in middle-aged women. Online brief interventions have shown efficacy with a wide range of populations and are both acceptable and effective with women (Bingham et al., 2011; Riper et al., 2008; Sundström, Blankers, & Khadjesari, 2017; A. White et al., 2010) hence our choice of medium and approach.

The Project's Objectives

The project was designed to reduce alcohol-related harm and raise awareness of the health risks of drinking among middle-aged women in the ACT. It aimed to achieve this through two approaches.

The first was the development and evaluation of an online intervention program managed largely by the research team at the Centre for Alcohol Policy Research (CAPR) outlined in this report. The second was a targeted awareness campaign managed by the Foundation for Alcohol Research and Education (FARE), which ran in conjunction with the launch of the randomised controlled trial (RCT) conducted to evaluate the effects of the online intervention program.

There were several objectives underpinning each of these approaches. The objectives of the intervention were:

1. To reduce alcohol use of intervention participants 10-30 per cent.
2. To increase motivation to reduce alcohol use among intervention participants by 40-50 per cent.

3. To determine the effectiveness of an innovative digital platform to deliver alcohol harm reduction messages to reduce alcohol use to middle-aged women in the ACT.

The objectives of the targeted awareness campaign were:

1. To increase motivation to reduce alcohol use among middle-aged ACT women by 10-20 per cent.
2. To increase awareness of long-term health risks among participants and middle-aged ACT women.
3. To determine the effectiveness of an awareness campaign to reduce alcohol use to middle-aged women in the ACT.

The results of the awareness campaign are not part of this report, which will exclusively focus on the results of the RCT. The objectives listed above were used to inform the study design outlined in the next section of this report.

Preparation for the Trial

In preparation for the trial and during the development stage of the study, the research team has written a protocol paper. This paper outlined in detail the methods, including the study design, participants, recruitment, procedures, the intervention used, outcomes, measures, data management and data analysis procedures. The protocol paper was used as a supporting document for the ethics application and later submitted for publication in a peer-reviewed journal (currently under review).

The ethics application for the randomised controlled evaluation study was submitted in July 2019 and later amended 30th October 2020 to reflect minor changes in the measurements included. The project received ethics approval from the La Trobe University Human Research Ethics Committee (HEC19938). The trial was also registered with Australia New Zealand Clinical Trials Registry (ANZCTR): ACTRN12620000814976 on 14 August 2020.

Co-design Process

Focus Group Workshops

Before developing the intervention, preliminary research showed a gap in the literature regarding Australian middle-aged women and their drinking practices. This included their behaviours, reasons and motivations for consumption. As there have been few attempts at alcohol-focused health promotion among older female drinkers, this information was needed to effectively tailor and target the planned intervention. Thus, to better understand middle-aged Australian women's drinking and to co-design a resource to help this age group of women reduce their drinking, focus group workshops were conducted. Ethics for this component of the study was approved by the La Trobe University Human Ethics Committee on 31st May 2019 (HEC19041).

We used convenience sampling to recruit participants; this involved paid advertisements promoting the study on Facebook, displayed in women's newsfeeds on desktop and mobile. Advertising was targeted towards women, aged 40-65 years in the metropolitan areas of Melbourne and Canberra. Participants who clicked on the ad were taken to a screening

survey, which assessed eligibility. Women were included if they consumed alcohol at least weekly and were fluent in English.

Workshop activities were designed in consultation with a user-experience designer. The activities were designed to encourage discussion about how alcohol fitted in with daily lives, motivations for drinking, where participants sought health information, who they would turn to for changing their behaviour, and knowledge of the health effects of alcohol. We developed the focus group workshops such that women participated in a co-design process to develop a resource about alcohol that they would use, and which would appeal to them.

In total, ten 3-hour workshops with a total of n=39 women aged 40-65 years were conducted. Workshop sizes varied from 3-9 participants. Eight workshops were conducted in Melbourne, Australia, on university or research institution premises between June and September 2019. Two workshops were conducted in Canberra, at FARE headquarters in October 2019.

Findings

Findings from the workshops suggested a variety of content and tools middle-aged women might like to see in an intervention, including:

- Reminders of what a standard drink is
- Most up to date evidence on the effects of alcohol from reliable, reputable sources
- Information about alternatives to alcohol
- Information on alternative activities they could do instead of drinking
- Normative feedback
- Associations between different levels of consumption and the consequences (calorie count, money spent, health impacts etc.)
- How to combat drinking pressure from friends and family
- Representations of real women in the resources, including diversity in size, age etc.
- Being able to track progress in reducing consumption over time
- A simple, easy to navigate tool

The workshops illustrated the need for strong messaging around safe drinking levels, as a large majority of women in the focus groups did not consider their drinking as problematic. To challenge perceptions, the intervention and awareness campaign needed clear and consistent messages.

Development of the Intervention Platform

In late 2018 and early 2019, the CAPR team began engaging an IT contractor with proven skills and experience to develop an innovative platform appropriate for middle-aged women. Extensive consultation occurred with the contractor, and contract negotiations were finalised in mid-March 2019. The process of building the platform commenced in the second half of March 2019, and the research team worked closely with the IT contractor to develop the intervention. Regular meetings were held with the research team and the IT contractor to discuss the requirements of the platform, provide feedback on draft platform components, and ensure consistency of the design with the requirements of our target group. This also included how and where participant data would be stored throughout the intervention, as

well as the requirements of the EMA and personalised participant feedback. The build of the SMS messaging system commenced in the last quarter of 2020. The messaging system aimed to feed individual data and change over time back to the participant. This was designed to increase their engagement with the intervention, develop tailored goals, reflect on their progress and revisit the website's content correspondingly (see the 'Ripple intervention).

Finalising 'Ripple'

The name 'Ripple' was chosen for the platform delivering the intervention because positive health and wellbeing outcomes from reducing alcohol use have a ripple effect on other aspects of women's lives. FARE developed a brand and associated colour palette for Ripple, including fonts, graphic elements and a logo.

Over the second half of 2020, the content was presented to women in the target group for feedback on presentation and wording. The feedback of these women was then incorporated into the intervention. In addition, extensive pre-testing was carried out by the research team and other internal staff. The technical pre-testing and content fine-tuning began once the platform was operational and continued over several months in 2020 to ensure its functionality and usability. When the platform was completed, the team began testing data download, SMS functionality, and created a welcome video to inform participants on how to use the platform and ensure participants about the confidentiality of their contributions to the intervention.

The work on the functionality and content such as questionnaires, interactive challenges, podcasts, and standard drinks advice was finalised and uploaded to the platform in early 2021.

Beta testing of the Ripple intervention continued during the first months of 2021, including refinements to the design, content and user experience based on this testing and feedback from the team at FARE. This involved continued discussions, checks and controls between the research team and IT contractor up until, and including, the early stages of the launch to ensure a smooth experience for all participants.

The 'Ripple' Intervention

The underlying theory for the online intervention is based on the assumptions of the Integrated Behavioural Model (Fishbein, 2009) and the Transtheoretical Model of Change (Prochaska & Diclemente, 1986). The Integrated Behavioural Model (Fishbein, 2009) posits that the most important determinant of behaviour is the intention to perform the behaviour, informed by individuals' attitudes, perceived norms and personal agency. However, within this model, intention to perform a behaviour is modified by four key factors: knowledge and skills, environmental constraints; the salience of the behaviour to the individual and the role of habits.

The Transtheoretical Model of Change (Prochaska & Diclemente, 1986) provides an integrative framework for understanding and intervening with human intentional behaviour change. The theory posits that individuals move through six stages of change, and for each stage, different behavioural change strategies will be effective. The intervention

operationalises principles from both theories and integrates concepts from the alcohol-specific behavioural literature to develop a comprehensive approach to changing alcohol use. The intervention is also based on the outcomes of interactive focus group workshops that were run by the research team with women aged 40-65.

The intervention was a web-based platform that participants in the intervention group could access through a link after completing their first EMA survey. Participants could jump in and out as they pleased and could see their progress over time. There were five key features of the intervention.

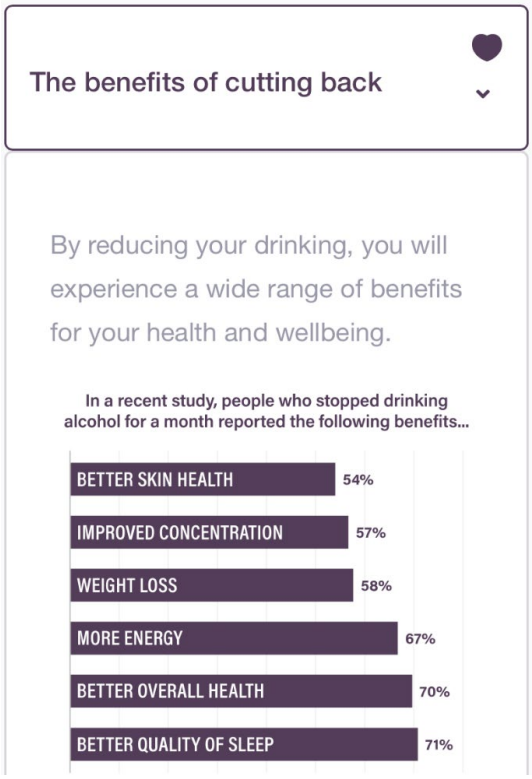
Goal setting: Participants were able to set goals at the start of the intervention period, and amend them throughout, for the reduction of their alcohol use. This included goals around what they wanted to achieve by reducing their consumption, how much they would like to reduce their drinking, barriers to reducing their consumption, and who might support their reduced drinking. These goals were designed to give participants a voice over what they hoped to achieve and acted as a sort of diary where they could reflect on their goals.

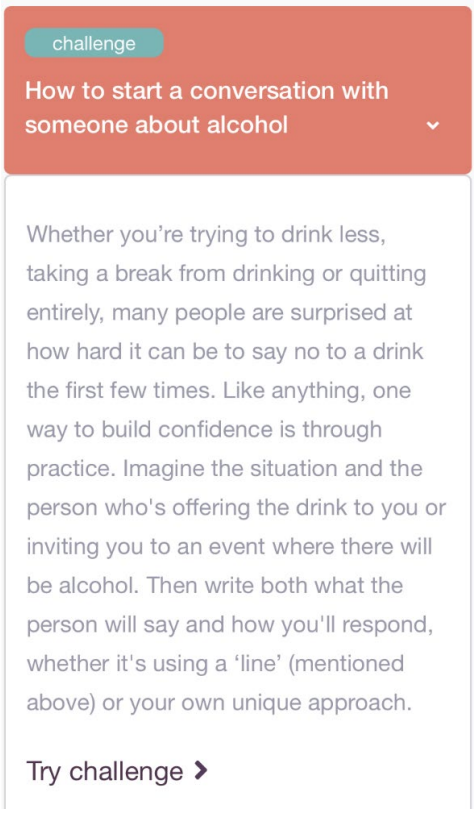
Tracking of alcohol use: Based on the data collected via EMA in their twice-weekly assessments participants could track their alcohol use in the intervention via a graph which updated after each assessment was completed. This was intended to help participants track progress and motivate them to continually reduce their drinking.

Personalised feedback: Each participant received personalised feedback on how their alcohol use was tracking via text messaging. This included congratulatory messages for those who had reduced their consumption, and supportive messages for those who had increased their consumption or consumed the same amount. The information provided was intended to encourage participants, to help them (re)engage with the content, and to motivate them based on their personal data tracking.

Modules of content: There were four modules on the platform, which provided participants with a large amount of content they could access at their choosing. Modules contained a variety of engaging content including fact sheets, tasks and podcasts with health experts. Participants could also select their favourite pieces of content within the modules to save on the home screen of the platform for easy access.

There were four modules in total: 1) *Reduce your risk*, which provided the most up to date evidence of the harms associated with alcohol use, information about what a standard drink is, an online calculator that allowed participants to measure their current level of consumption and receive feedback on the associated costs and harms; 2) *Mindfulness and cutting back*, which contained information about drinking motives, and provided participants with skills to both learn to consume alcohol mindfully, as well as apply the broader technique of mindfulness to their lives to reduce the common antecedents of alcohol use (e.g. stress); 3) *Drinking when socialising*, which explored the social influences on drinking, including facts about how people influence each other both consciously and unconsciously, encouraged participants to reflect on where alcohol currently fits into their social lives, and helped build participant's skills to talk about their alcohol use with others, and 4) *Alcohol is everywhere*, which looked at the broader factors that influence alcohol use, including information about the normativity of alcohol in Australian society and how alcohol availability and outlet density impact on consumption, the ways in which the alcohol industry specifically target women, how alcohol advertising impacts on children, and the broader alcohol industry tactics used to promote their products.





Challenges: Challenges were available at the end of each module, allowing participants to operationalise their learnings in the real world. For example, participants were challenged with the task of measuring changes in their sleep over time, thinking of alternative activities that they could replace drinking with, learning how to decline alcohol in social situations, and reflecting on how alcohol advertising might have influenced them. Challenges were designed to provide participants with practical tools they could draw on to reduce their drinking, as well as further engaging them in content and teaching skills that they could draw on beyond the intervention.

Trial Overview

Participants

Participants were eligible for the study if they were aged between 40-65, identified as female, resided in the ACT or a surrounding postcode (which covers the ACT), were able to understand written English, were able to provide informed consent, owned a mobile phone with SMS capabilities, had access to the internet, and consumed alcohol at least weekly OR consumed four or more standard drinks at least once a month. Potential participants were excluded if they were currently receiving treatment for a substance use disorder, or not in Australia for the duration of the study. In total 205 women in the target group (40-65-year-old women living in the ACT) were recruited to the study (see Table 1 below).

Recruitment

The trial officially launched on March 30, 2021, supported by a launch campaign by FARE which was used to create additional awareness of the trial. Study recruitment was carried out by FARE using both online and offline approaches. CAPR provided the team at FARE with suggestions for access points and areas for recruitment and contributed to the messaging of the recruitment around the trial.

Due to the compressed timeframe for completing the project, the campaign for recruiting participants to the trial was combined with the awareness-raising health promotion campaign (also part of the funded project). For this combined campaign, FARE developed a Ripple microsite and a communications strategy which used social media (Facebook, Instagram) to drive people to the website which housed a recruitment page. Traditional media and stakeholder engagement also encouraged participation in the trial.

Social and other media featured short videos of Canberra women from the target group delivering messages about the harms of alcohol use, the benefits of cutting back, and a call to learn more and consider signing up for the trial by visiting the website.

Specific recruitment strategies and outcomes included:

- On launch, an Electronic Direct Mail was sent to 200 Canberra residents on FARE's subscriber list. This achieved a very high open rate of 50%.
- In the days following launch, emails containing information about the campaign and links to resources were sent to 60 ACT stakeholders (from a list developed in conjunction with CAPR).
- During the campaign period from 30 March to 31 May, 16 Ripple ads were promoted on Facebook and Instagram, with a reach of nearly 195,000 over more than 360,000 impressions. Half of the ads were specifically aimed towards recruitment of trial participants.
- The campaign generated 4,040 visits to the website recruitment page and 8,667 page views overall. Peak views of the recruitment page were in May, with 1,600 in the first fortnight in May and 1,012 in the second fortnight.

- Ripple videos were broadcast in GP surgeries, reaching 150,000 waiting room visitors between mid-April and 30 June. The videos were played a total of 37,620 times.
- In May, 4,000 flyers designed to encourage enrolment to the trial were mailed out to GP surgeries, hospitals, community health centres and other community groups.
- Two postings were made during the campaign to a Canberra community notice board about Ripple.
- Presentation about Ripple to a peer support network of about 20 community workers.
- Worksafe ACT published information on Ripple in their Healthier Work e-newsletter, sent to all ACT Government employees on 1 June.

Recruitment was rolling such that participants were recruited continuously while the intervention was running. The last participants in the trial enrolled on 16th June 2021. Details on participant enrolment are given in the next section.

Participant Enrolment over time

Participant signed up for the Ripple intervention between 1 April and 16 June 2021. Figure 1 (below) gives an overview of the number of participants joining the trial on any given day. Two participants joined after the deadline of 31 May (10 June and 15 June) but were not excluded from the trial to increase the test power of the evaluation.

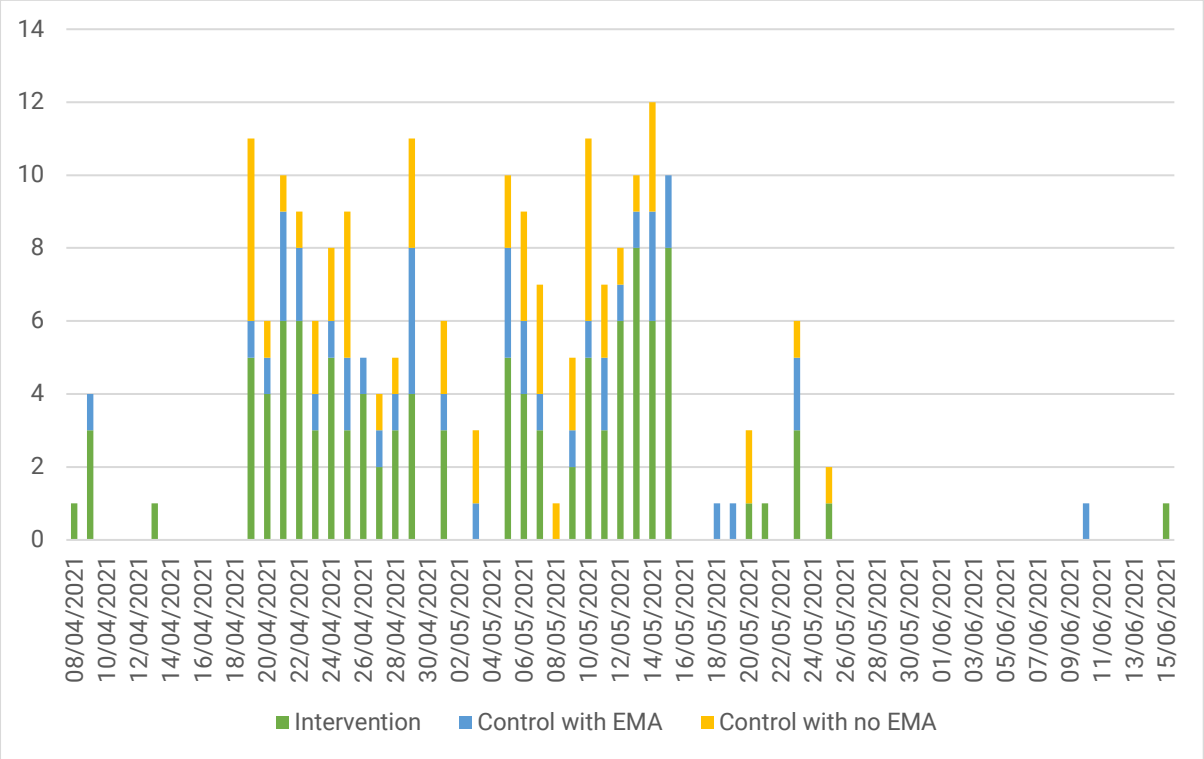


Figure 1: Number of participants recruited over time, by group.

Monitoring and Feedback

During the study, the research team monitored the progress of recruitment, answered questions from participants and corrected minor errors in the messaging. Participants were also able to provide feedback and alert the research team of any technical issues occurring during the study. The research team monitored the feedback closely and continued to work with the IT contractor to manage any technical difficulties throughout the trial. Most requests from participants were centred around difficulties uploading the data from their baseline assessment. These difficulties were almost exclusively linked to women signing up via professional networks not allowing data upload. These participants were advice to retry the upload once they are locked into private networks. A small number of women (<5) withdraw their consent during the duration of the trial and their data was deleted.

Study Design

The main study trialling the intervention was designed as a three-arm randomised controlled trial (RCT). Within RCTs participants are randomly assign into control and intervention groups and this study design is appropriate for determining the effectiveness of an experimental intervention. For this study, the RCT assigned eligible participants to one of three groups, outline below. All groups were required to fill in a baseline questionnaire and an eight-week follow-up questionnaire. Two groups completed twice-weekly surveys of alcohol use using Ecological Momentary Assessment (EMA) sent via text messages on Mondays and Thursdays for 8 consecutive weeks. Only one group had access to the Ripple intervention. These three groups were labelled:

- **Intervention**: the group that had access to the online intervention, received two weekly text message surveys (EMA) and completed a baseline and follow-up assessment
- **Control with EMA**: the control group that received two weekly text message surveys (EMA) and completed a baseline and follow-up assessment
- **Control without EMA**: the control group that only completed a baseline and follow-up assessment

The aim was to achieve a 50-25-25 split between three different groups: 50% in the Intervention group, 25% in the Control with EMA group, 25% in the Control without EMA group. The randomisation of participants occurred as soon as participants qualified for the trial and was done automatically by an algorithm linked to the website.

The final sample resulted in a slightly different split from the assumed 50:25:25. This slightly different distribution was linked to the automatic randomisation and would be less pronounced in a larger sample. The actual split of the three groups was as follows Intervention group (n=110; 53.6% of all women recruited); Control with EMA group (n=43; 21% of all women recruited); and Control without EMA group (n=52; 25.4% of all women recruited).

Demographic details and distribution within the three groups is given in Table 1 (below).

	Intervention		Control with EMA		Control without EMA		Total	
	%	n	%	n	%	n	%	n
Age								
40-44 years old	20.0%	22	20.9%	9	19.2%	10	20.0%	41
45-49 years old	28.2%	31	11.6%	5	26.9%	14	24.4%	50
50-54 years old	24.5%	27	23.3%	10	19.2%	10	22.9%	47
55-59 years old	13.6%	15	18.6%	8	26.9%	14	18.0%	37
60-65 years old	13.6%	15	25.6%	11	7.7%	4	14.6%	30
Education								
Did not complete secondary school	0.0%	0	2.3%	1	1.9%	1	1.0%	2
Complete secondary school	8.2%	9	4.7%	2	11.5%	6	8.3%	17
Diploma/TAFE certificate	18.2%	20	9.3%	4	17.3%	9	16.1%	33
Bachelor's Degree	38.2%	42	53.5%	23	32.7%	17	40.0%	82
Postgraduate degree	35.5%	39	30.2%	13	36.5%	19	34.6%	71
Employment								
Unable to work	0.9%	1	2.3%	1	1.9%	1	1.5%	3
Retired	10.0%	11	16.3%	7	1.9%	1	9.3%	19
Unemployed	0.9%	1	0.0%	0	1.9%	1	1.0%	2
Focusing on home-duties	4.5%	5	2.3%	1	1.9%	1	3.4%	7
Self-employed	8.2%	9	7.0%	3	5.8%	3	7.3%	15
Casually employed	3.6%	4	2.3%	1	3.8%	2	3.4%	7
Part-time employed	19.1%	21	11.6%	5	23.1%	12	18.5%	38
Full-time employed	52.7%	58	58.1%	25	59.6%	31	55.6%	114
Personal income								
Prefer not to say	1.8%	2	7.0%	3	3.8%	2	3.4%	7
Nil income	0.9%	1	2.3%	1	1.9%	1	1.5%	3
$1-$149/week	1.8%	2	0.0%	0	1.9%	1	1.5%	3
$150-$249/week	0.0%	0	2.3%	1	0.0%	0	0.5%	1
$250-$399/week	0.9%	1	0.0%	0	1.9%	1	1.0%	2
$400-$599/week	2.7%	3	4.7%	2	0.0%	0	2.4%	5
$600-$799/week	2.7%	3	7.0%	3	0.0%	0	2.9%	6
$800-$999/week	2.7%	3	2.3%	1	1.9%	1	2.4%	5
$1,000-$1,299/week	6.4%	7	2.3%	1	7.7%	4	5.9%	12
$1,300-$1,599/week	12.7%	14	16.3%	7	5.8%	3	11.7%	24
$1600-$1999/week	15.5%	17	11.6%	5	25.0%	13	17.1%	35
$2,000 or more/week	51.8%	57	44.2%	19	50.0%	26	49.8%	102

Table 1: Socioeconomic characteristics by intervention and control group with and without EMA, % and sample size (n)

	Intervention		Control with EMA		Control without EMA		Total	
	%	n	%	n	%	n	%	n
Marital Status								
Single	8.2%	9	9.3%	4	5.8%	3	7.8%	16
Widowed	3.6%	4	0.0%	0	0.0%	0	2.0%	4
Divorced	15.5%	17	9.3%	4	25.0%	13	16.6%	34
Separated (but not divorced)	4.5%	5	7.0%	3	9.6%	5	6.3%	13
Married (including de facto or living with partner)	68.2%	75	74.4%	32	59.6%	31	67.3%	138
Dependent children								
No	40.9%	45	51.2%	22	48.1%	25	44.9%	92
Yes	59.1%	65	48.8%	21	51.9%	27	55.1%	113
Total	**53.6**	**110**	**21.0**	**43**	**25.4**	**52**	**100**	**205**

Table 1: Socioeconomic characteristics by intervention and control group with and without EMA, % and sample size (n), continued

Baseline and Follow-up Assessment

The baseline assessment was the first survey participants completed when they signed up for Ripple, while the follow-assessment was completed 8 weeks later. Aside from some initial screening questions and a question asking participants how they learned about the trial (only in the baseline assessment), both assessments were the same. They also recorded demographic data at both timepoints, including employment status, highest level of education, marital status, income, smoking status and dependent children.

To evaluate the primary outcomes for the trial – whether the intervention reduces alcohol use – several alcohol use measures were used. These included:

- Last week drinking
- Typical drinking
- Heavy episodic drinking (4 or more standard drinks)

To evaluate the secondary outcomes for the trial:

- Alcohol-related consequences
- Knowledge of short and long-term harms alcohol-related harms
- Motivation to reduce alcohol use (Readiness to change)
- Mental health
- Self-efficacy

Ecological Momentary Assessment (EMA)

Ecological Momentary Assessment (EMA) involves repeatedly measuring participants' behaviours and attitudes in real time in naturalistic environments. For this trial, EMA surveys

were sent out via text message twice-weekly – once on Monday and once on Thursday – over 8 weeks. The EMA measured:

- Daily alcohol use (since the previous EMA)
- Recent stress
- Self-efficacy
- Social support/loneliness

Because repeated self-reporting can influence drinking behaviour and result in lower alcohol use due to increased awareness generated by repeated measurement (Kuntsche & Robert, 2009), EMA was not only used within the intervention group to allow participants to track their alcohol use but also in one of the two control groups (control with EMA.

Measures and Analyses

Analyses

Analyses in the context of this report will focus on baseline and 8-week follow-up measures. This approach guarantees the comparability of measures across all three arms of the randomised control trial: Intervention group, control group with EMA and control group without EMA. As mentioned earlier the differentiation between the two different control groups allows to distinguish the possible effect of asking participants repeatedly about their alcohol use, which may have increased awareness of drinking and thus may have had an intervention effect in itself (Kuntsche & Robert, 2009). Due to the limited number of participants and to allow comparisons of all three groups the individual EMA measures across the 8 weeks of the intervention will not be included in the reporting.

We noted a significant attrition in the number of respondents at follow-up. While 205 women joined the trial and completed the baseline assessment (n=205) only 69 participants completed the follow-up assessment. Of those 69 women, 31 were assigned to the intervention group, 17 to the control group with EMA and 21 to the control group without EMA. This high level of attrition had wide-ranging implications on the interpretation and testing of the effectiveness of the study due to the limited test power at 8-weeks follow-up. An outline of the difference between those who remained in the trial versus those who dropped out as well as the implications this has on the evaluation is given below in '**Sample at Follow-up and Attrition**'.

The evaluation of intervention effects followed the intention to treat principle. Following this approach baseline data from all women signing up for the trial (n=205) was compared with women providing data at 8-week follow up (n=69). The missing information for the 136 women not providing follow-up data was replaced with by the mean. Linear regression models were used to analyse group differences between the three arms of the trial, in which the control group without EMA served as reference. Outcome variables were primary and secondary outcomes measures (details given below) at follow-up adjusted for baseline assessment.

For the reporting of the results in this report, changes will be presented visually in the main body of this report to best illustrate developments within the three groups. Significant results will be marked as such in the text. For results not obtaining statistical significance no test will be given. Detailed information and significance testing can be found in the Appendix Tables to this report. As previously mentioned, the limited number of respondents at follow-up and the conservative approach of the intention to treat principle resulted in very few significant results due to the lack of test power in the present sample.

The figures presented in the Result section of this report will not only include the difference between the full sample at baseline (n=205) and women completing the 8-week follow-up (n=69) but also the baseline measures of those who completed the follow-up (n=69). All figures below include therefore three groups: a 'baseline' group (all 205 women who joined the trial), a 'baseline continuing' group (all 69 women who remained in the trial) and a 'follow-up' group. The Appendix Tables also provide details for all three groups. To distinguish the

baseline measure of those who provided data at follow up from the full sample, bar diagrams related to the 'baseline continuing' group will be shaded.

Primary and Secondary Outcome Measures

The primary aim of the present evaluation was to test the effectiveness of the intervention in reducing both the frequency of alcohol use, as well as the alcohol intake per occasion among middle-aged women. Secondary aims included testing the effectiveness of the intervention in reducing alcohol-related consequences, increasing knowledge of the harms associated with alcohol use (long-term and short-term), increasing motivation to reduce alcohol use, improving reported mental health, and increasing self-efficacy.

Primary Outcome: Alcohol Use

Change in alcohol use during the 8-week trial was measured via the following five indicators:

The first was **last week's alcohol use**: "Thinking back over the last week, how many standard drinks containing alcohol did you have on each day of the week?". Participants were able to select from a 7-point scale ranging from 0 (none) to 6 (6 drinks or more) for each day of the week (Monday to Sunday). By summing up the individual reports for all seven days were used to create the indicator for last week's alcohol use.

The second measure was the **alcohol use in a typical week**: "Now thinking about a typical week, how many standard drinks would you consume on a typical…". Participants were able to select from a 7-point scale ranging from 0 (none) to 6 (6 drinks or more) for each day from Monday to Sunday. As for the first indicator the number of drinks reported was summarised across all days of the week to create an indicator of alcohol use in a typical week.

Based on the information provided for the alcohol use in a typical as well as the last week two additional indicators were created by summarising all days the respondent reported alcohol use to gain an indication of the **frequency of drinking in a typical week** and the **frequency of drinking in the last week**.

The last measure was the **frequency of heavy episodic drinking**: "In the last 12 months, how often have you had 4 or more standard drinks on one occasion?". Participants could select from seven answer categories ranging from never to every day. Answer categories were translated into annual frequencies with mean values used for categories providing a range (e.g., 3-4 days a week = 3.5 days per week = 3.5 * 52 = 286).

For all alcohol use related questions, participants were provided information of what comprised a standard drink

Secondary Outcome: Alcohol-related Consequences

To measure alcohol-related consequences, 12 items from the Rutgers Alcohol Problem Index (RAPI) (H. R. White & Labouvie, 1989) and 9 items from the Young Adult Alcohol Consequences Questionnaire (YAACQ) (Read, Kahler, Strong, & Colder, 2006) were used based on their age-appropriateness for our target group.

Participants were asked "How many times has this happened to you while you were drinking or because of your drinking during the last year?: "Got into fights with other people", "Neglected your responsibilities", "Missed out on other things because you spent too much money on alcohol", "Caused shame or embarrassment to someone", "Friends or relatives avoided you", "Felt that you needed more alcohol than you used to in order to get the same effect", "Tried to control your drinking", "Had withdrawal symptoms, that is, felt sick because you stopped or cut down on drinking", "Noticed a change in your personality", "Drove a car when you knew you had too much to drink to drive safely", "Drank more than you originally planned", "Felt guilty about your drinking", "Not eaten properly because of your drinking", "Ended up drinking on nights when you had planned not to drink", "Often found it difficult to limit how much you drink", "Have not slept properly", "Have not been as sharp mentally", "Had less energy or felt tired", "Missed a day (or part of a day) of work", "Kept drinking when you promised yourself not to" and "Felt physically or psychologically dependent on alcohol". There were four possible answer categories ranging from 0 (none) to 3 (more than 5 times). Responses were dichotomised 0 (none) vs 1 (at least once) and summarised across all 21 items resulting in a scale ranging from 0 (no harm reported in the last 12 months) to 21 (report of all 21 items at least once in the past 12 months).

Secondary Outcome: Knowledge of Short-term Alcohol-related Harms

As no validated scale currently exists to measure knowledge of alcohol harms, knowledge of short-term alcohol-related harms was taken from the scale used in Coomber et al.'s (2017) study. They were measured with the question "Which of the following do you think are likely consequences of having 5 alcoholic beverages in a single occasion?", with participants asked to rank the likelihood of the following consequences: "Lack of coordination and slower reflexes", "Reduced concentration", "Motor vehicle, bicycle and pedestrian accidents", "Injuries associated with falls, accidents, violence and intentional self-harm", "Alcohol poisoning", "Drownings", "Coma and/or death" and "Harm to unborn babies". There were five possible answer categories ranging from 0 (highly unlikely) to 4 (highly likely). Responses were recoded to indicate endorsement (likely, highly likely coded as 1) versus opposition or indifference (highly unlikely, unlikely, unsure coded as 0) and summarised across all eight items. The resulting scale ranges from 0 to 8 whereby higher values indicate a higher endorsement and thus higher knowledge of short-term harms.

Secondary Outcome: Knowledge of Long-term Alcohol-related Harms

Knowledge of long-term alcohol-related harms was taken from the scale used in Coomber et al.'s (2017) study. They were measured with the question "Which of the following do you think are likely consequences of consuming 10 or more standard drinks a week?" with participants asked to rank the likelihood of the following consequences: "Harm to unborn babies", "Cirrhosis of the liver", "Brain damage", "Stomach problems", "Heart and blood disease", "Pancreatitis", "Bowel cancer", "Pharyngeal cancer", "Oesophageal cancer", "Mouth cancer", "Larynx cancer", "Breast cancer", "Stroke" and "Mental health problems". There were five possible answer categories ranging from 0 (highly unlikely) to 5 (highly likely). Responses were recoded to indicate endorsement (likely, highly likely coded as 1) versus opposition or indifference (highly unlikely, unlikely, unsure coded as 0) and summarised across all 14 items. The resulting scale ranges from 0 to 14 whereby higher values indicate a higher endorsement and thus higher knowledge of long-term harms.

Secondary Outcome: Motivation to Reduce Alcohol Use (Readiness to Change)

Readiness to change was measured using the 12-item Readiness to Change Questionnaire (RCQ) (Heather & Rollnick, 1993). The questionnaire describes the stages a person moves through to reduce their alcohol use including "Precontemplation" (PC), "Contemplation" (C) and "Action" (A). Participants were asked "Please rate how much you agree with the following statements" and ranked their agreement with the following statements: "I don't think I drink too much" (PC), "I am trying to drink less than I used to" (A), "I enjoy drinking, but sometimes I drink too much" (C), "Sometimes I think I should cut down on my drinking" (C), "It's a waste of time thinking about my drinking" (PC), "I have just recently changed my drinking habits" (A), "Anyone can talk about wanting to do something about drinking, but I am actually doing something about it" (A), "I am at the stage where I think I should drink less alcohol" (C), "My drinking is a problem sometimes" (C), "There is no need for me to think about changing my drinking" (PC) and "Drinking less alcohol would be pointless for me" (PC) (one item was removed as it was deemed inappropriate in the context of the intervention – "I am actually changing my drinking habits right now" (A)). There were five possible answer categories ranging from 1 (strongly disagree) to 5 (strongly agree). Following the coding scheme of the RCQ, responses were recoded with disagreement being coded negatively (strongly disagree: -2, disagree: -1) and agreement positively (strongly agree: 2, agree: 1). Unsure responses were coded as 0. The scale score varies between -8 and 8 (-6 and 6 for 'Action'), where positive values represent an overall agreement with the items of the relevant subscale and negative scores represent a disagreement with the items.

Based on the Theory of Readiness of Change Precontemplation represents a decreasing readiness to change thus negative values on this scale are favourable to change. For both the Contemplation and the Action scale positive values indicate a higher readiness to change.

Secondary Outcome: Mental Health

Mental health was measured using the 5-item Mental Health Inventory (MHI-5) (Berwick et al., 1991). Participants were asked "How often in the last month, have you:" and ranked how often the following had happened: "Been a very nervous person", "Felt calm and peaceful", "Felt downhearted and blue", "Been a happy person" and "Felt so down in the dumps that nothing could cheer you up". There were five possible answer categories ranging from 0 (never) to 4 (very often). The two positive items ("Felt calm and peaceful" and "Been a happy person") were coded inversely and responses were summarised across the five items resulting in a scale ranging from 0 to 20, with higher values indicating lower mental wellbeing.

Secondary Outcome: Self-efficacy

Self-efficacy was measured using the 10-item General Self-Efficacy Scale (Schwarzer & Jerusalem, 1995). Self-efficacy was measured with the following statements: "I can always manage to solve difficult problems if I try hard enough", "If someone opposes me, I can find the means and ways to get what I want", "It is easy for me to stick to my aims and accomplish goals", "I am confident that I could deal efficiently with unexpected events", "Thanks to my resourcefulness, I know how to handle unforeseen circumstances", "I can

solve most problems if I invest the necessary effort", "I can remain calm when facing difficulties because I can rely on my coping abilities", "When confronted with a problem, I can usually find several solutions", "If I am in trouble, I can usually think of a solution" and "I can usually handle whatever comes my way". Answer categories ranged from 0 (not at all true) to 3 (exactly true). By summing responses across the 10 items the indicator for self-efficacy has a value range from 0 to 30, with higher values indicating a higher self-efficacy.

Sample at Follow-up and Attrition

Data collection finished in late August 2021. After a consultation about retention rates, the research team noticed a significant drop at follow-up assessment (n=56). With the aim to increase the test power of the trial, the team sent a reminder message to all women enrolled in the study asking them to fill in the follow-up questionnaire. As a result, 13 women who did not respond to earlier messages provided follow-up data, resulting in a final sample of 69 women at follow-up. The attrition rate of the present study was 66.3% (n=136) of the original sample of 205 women signing up for the trial.

Given the already limited number of women participating at baseline, this means data at follow-up was only obtained from 33.7% of the original sample (n=69). Factors that may have impacted the retention of women in the study will be discussed later in this report.

Table 2 (below) compares the baseline characteristics of participants who left the trial (dropped out) with those who remained in the study and provided data at follow-up. None of the differences listed below obtained statistical significance (see Appendix Tables A3 and A4 for details). However, due to the small sample size differences in continuing and discontinuing women will be included in the presentation of results as outlined in the Analyses section of the report.

Table 2 illustrates that while women remaining in the study did not differ tremendously in age, educational level or marital status, those working full-time or having dependent children reported higher somewhat higher dropout rates. However, none of the differences observed was statistically significant.

Table 3 illustrates the difference in primary and secondary outcome measures for the two groups at baseline. Women continuing in the study and those quitting the trial after baseline did not differ substantially in the secondary outcome measures and none of the differences given in Table 3 obtained statistical significance (see Appendix Table A4).

	Baseline assessment	Participants who dropped out (n=136)	Participants who remained (n=69)
Age of the respondent	44-49	19.9%	20.3%
	50-54	27.2%	18.8%
	55-59	22.8%	23.2%
	60-64	16.2%	21.7%
	65+	14.0%	15.9%
Highest level of education	no secondary education	0.7%	1.4%
	completed secondary	8.1%	8.7%
	Diploma/TAFE	16.2%	15.9%
	Bachelor	40.4%	39.1%
	Postgraduate	34.6%	34.8%
Employment situation	unable to work	1.5%	1.4%
	retired	8.1%	11.6%
	unemployed	0.7%	1.4%
	home duties	2.9%	4.3%
	self-employed	6.6%	8.7%
	casual	3.7%	2.9%
	part-time	17.6%	20.3%
	full time	58.8%	49.3%
Dependent children	no	42.6%	49.3%
	yes	57.4%	50.7%
Marital status	single	6.6%	10.1%
	widowed	1.5%	2.9%
	divorced	16.2%	17.4%
	separated	7.4%	4.3%
	married	68.4%	65.2%
Intervention group	Intervention	58.1%	44.9%
	Control with EMA	19.1%	24.6%
	Control without EMA	22.8%	30.4%

Table 2: Demographic characteristics of participants at baseline, by retention in the study at 8-week follow-up.

	Baseline assessment	Participants who dropped out (n=136)	Participants who remained (n=69)
		mean	mean
Alcohol use	Number of standard drinks in a typical week	16.9	17.6
	Number of standard drinks in the last week	16.4	17.3
	Frequency of drinking in a typical week	5.1	4.9
	Frequency of drinking in the last week	5.0	4.5
	Frequency of heavy episodic drinking (4 standard drinks or more)	127.1	121.5
Alcohol-related consequences		11.3	12.1
Alcohol-related knowledge of harm	Short-term harm	5.9	6.0
	Long-term harm	9.2	9.2
Readiness to change	Pre-contemplation	-4.9	-4.3
	Contemplation	4.7	4.4
	Action	1.1	1.3
Mental health		8.1	7.8
Self-efficacy		21.6	20.6

Table 3: Primary and secondary outcome measures at baseline, by retention in the study at 8-week follow-up.

Results

Results for Primary and Secondary Outcomes

In the following, graphical representations of the changes in primary and secondary outcomes will be given for all three groups of the present RCT (intervention group, control group with EMA and control group without EMA). As mentioned in the Analysis section of this report and following the intention to treat principle, results will be given for all women participating at baseline (n=205) and women answering the follow-up (n=69). Significance tests for these comparisons can be found in the Appendix Tables A1 (primary outcomes) and A2 (secondary outcomes). Significant results will also be described in the text.

As outlined before women remaining in the trial from baseline to follow-up (n=69) will be included in all graphs (shaded bars). This allows us to highlight baseline differences between those who remained in the trial compared to those who dropped out. In our reporting for this study, we will primarily focus on the changes between all women providing data at baseline and those completing the follow-up survey. However, the authors will highlight pronounced differences among those who dropped out of the study compared to those remaining, although none of these differences obtained significance.

Primary Outcome: Alcohol Use

Alcohol Use in the last Week

Figure 2 (below) shows changes in the **number of standard drinks in the last week**.

At baseline women in the control group with EMA reported a higher number of standard drinks than women in any other group. This effect occurred randomly as group participation was based on automatic randomisation.

At follow-up all three groups reported a reduction in the number of standard drinks compared to baseline. This reduction was most pronounced in the intervention group and control group with EMA. The intervention group reported more than 6 drinks less per week compared to baseline (reduction of 38%) and a reduction of almost 7 standard drinks was reported in the EMA group (reduction of 36%). The reduction in the control group without EMA was negligible (<0.5 standard drinks). The reduction in the intervention group compared to the control group without EMA obtained statistical significance (B= -2.119, SE=1.021, p=0.039) while the difference between the control group with EMA compared to without EMA resulted in a marginal significance (B=-2.327, SE=1.252, p=0.065).

When comparing baseline results for continuing and quitting participants those continuing in the intervention and control group with EMA reported a slightly lower number of standard drinks while participants of the control group without EMA reported a somewhat higher number of standard drinks than the original sample.

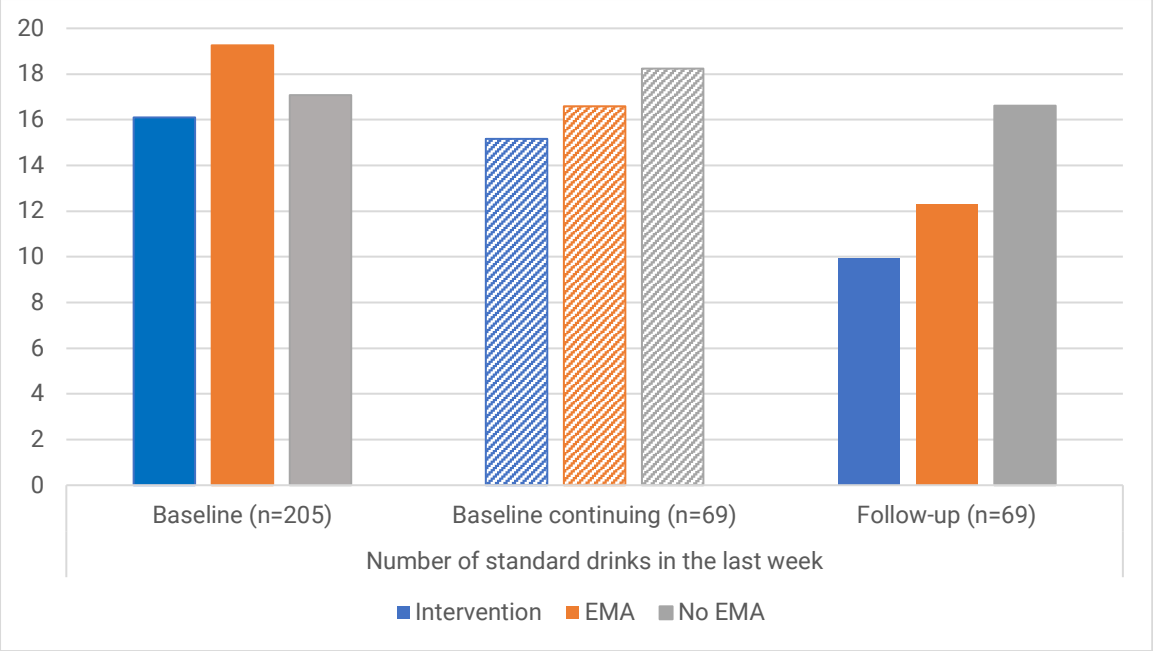


Figure 2: Alcohol use in the last week (number of standard drinks) at baseline and follow-up, by treatment group.

Figure 3 shows changes in the **drinking frequency in the last week**. At baseline, all three groups reported alcohol use between 4 to 5 days a week. This changed at follow-up; women in the intervention group reported a reduction in their drinking frequency of about 1.6 days (34%), while women in the control group with EMA reported a mean reduction of about 1.2 days (23%). Women in the control group without EMA drank about 0.7 days (15%) less often than at baseline.

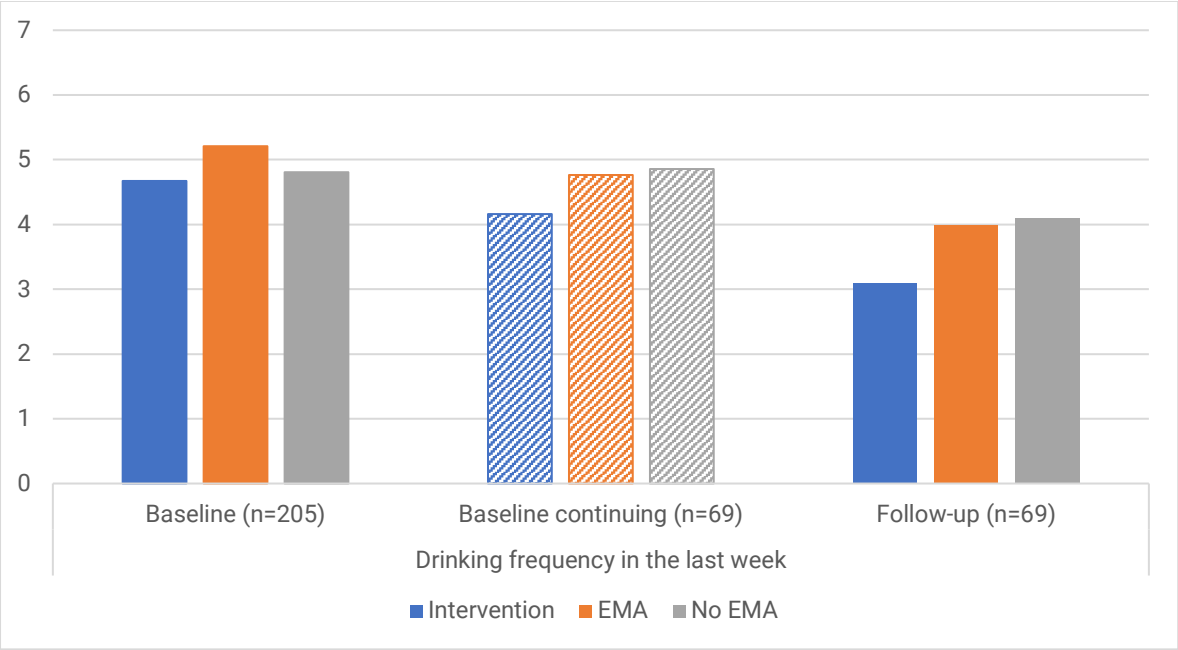


Figure 3: Frequency of alcohol use in the last week (number of days) at baseline and follow-up, by treatment group.

Alcohol Use in a typical Week

Figure 4 shows changes in alcohol use during a typical week.

At baseline women in the control group with EMA reported a slightly higher **number of standard drinks per typical week** than women in the other groups. At follow-up there was a decrease for all three treatment groups in a typical week drinking over the 8 weeks of the trial. This was greatest in the EMA-only group (4.7 standard drinks, 24%) and the intervention group (4.2 standard drinks, 24%) and least pronounced in the control group without EMA (2.2 standard drinks, 13%).

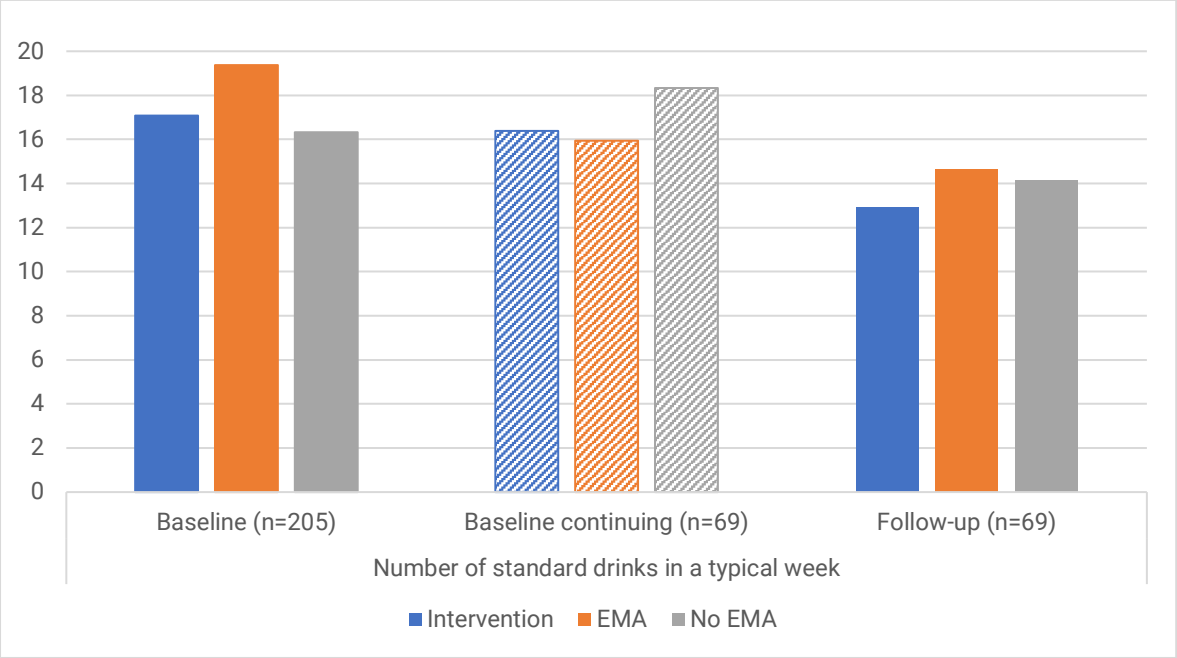


Figure 4: Alcohol use in a typical week (number of standard drinks) at baseline and follow-up, by treatment group.

Participants in the control group without EMA continuing in the study reported a higher number of standard drinks than the overall baseline sample.

Figure 5 illustrates the changes in the **drinking frequency in a typical week** between baseline and 8-week follow-up. At baseline, all three groups reported alcohol use on about 5 days a week. At follow-up women in the intervention group reported a reduction in their drinking frequency of about 1.3 days (25%), while women in the control group with EMA reported a mean reduction of about 0.8 days (15%). Women in the control group without EMA drank about 1 day less often (20%) compared to baseline.

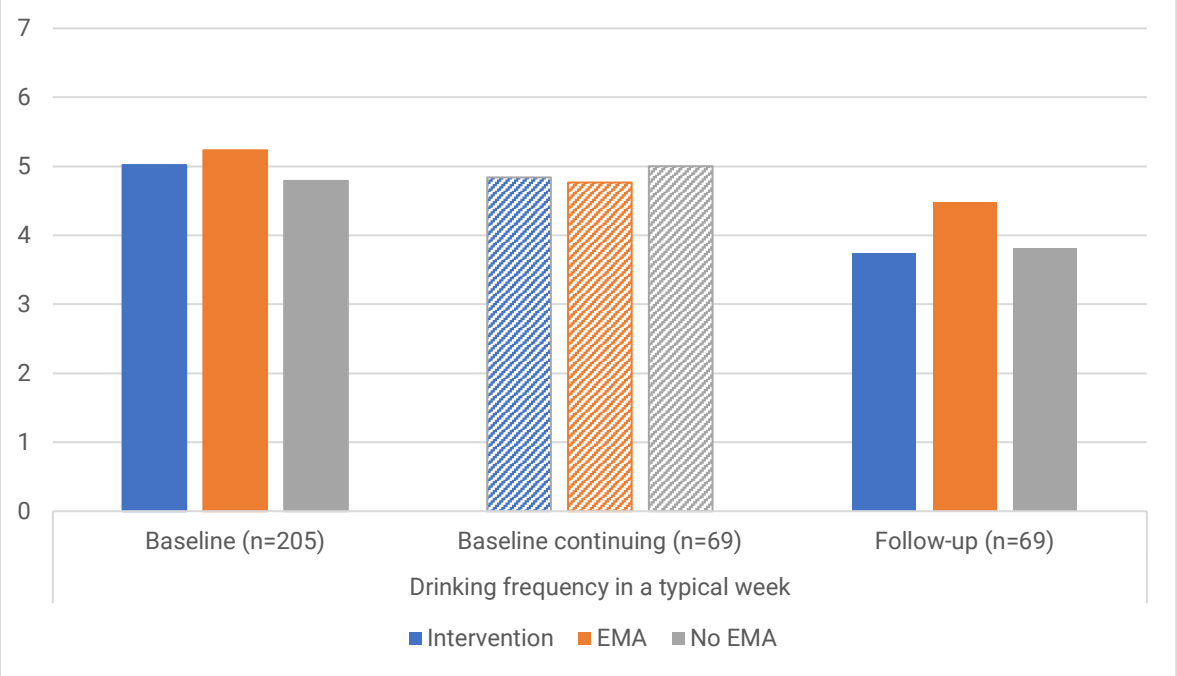


Figure 5: Frequency of alcohol use in a typical week (number of days) at baseline and follow-up, by treatment group.

Heavy episodic Drinking (≥4 or more Standard Drinks)

Figure 6 below indicates a difference between the three treatment groups regarding the **frequency of heavy episodic drinking over the past 12 months**.

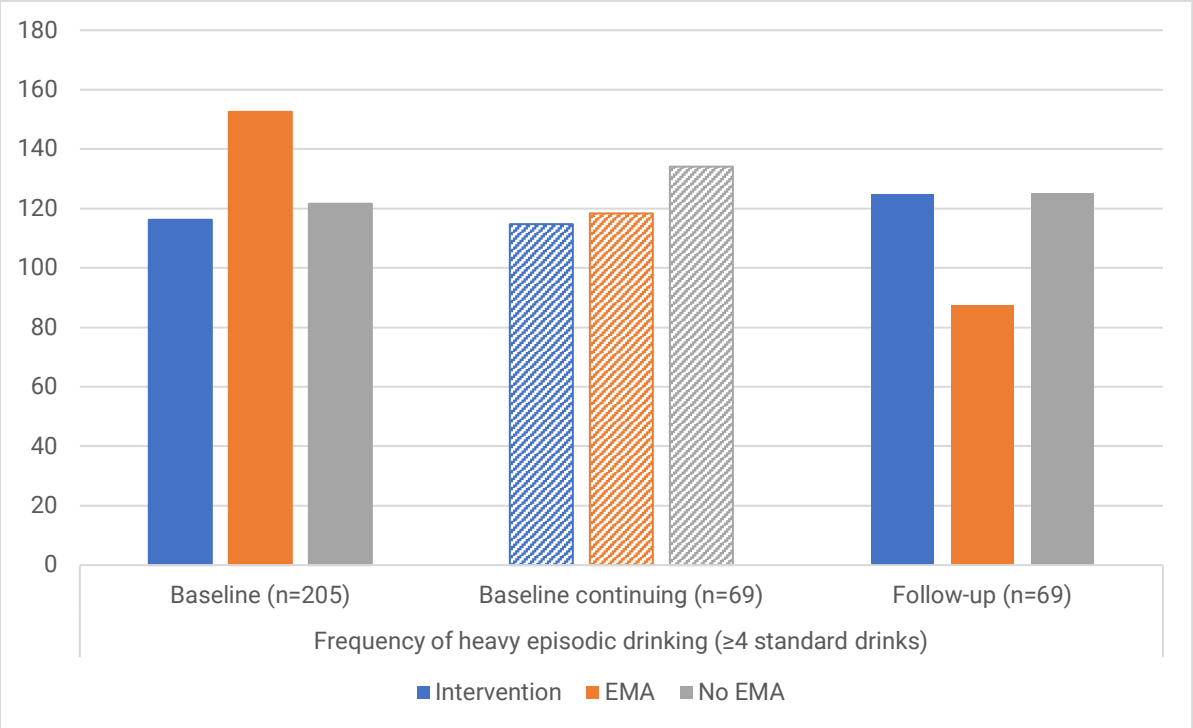


Figure 6: Annual frequency of heavy episodic drinking (≥ 4 standard drinks) at baseline and follow-up, by treatment group.

Women in the control group with EMA reported the highest frequency at baseline but also the most pronounced drop at follow-up (43%). Frequencies for both the intervention group as well as the control group without EMA remained largely unchanged.

The comparison between the two baseline groups reveals that the substantial and marginal significant drop in the control group with EMA (B=-21.810, SE=12.499, p=0.083) seems to be mainly due to women continuing in the trial reporting a lower annual frequency of heavy drinking at baseline compared to the full sample of women signing up for the trial.

Secondary Outcomes

Alcohol-related Consequences

Figure 7 shows the mean scores for each treatment group on alcohol-related consequences. At follow-up reporting of alcohol-related consequences increased significantly in the intervention group (B=0.843, SE=0.353, p=0.018). No change was found for those in the control groups with and without EMA. The increase in the intervention group can potentially be explained by increased knowledge of alcohol-related harms and, therefore, a greater likelihood to acknowledge the impact alcohol had on their health, wellbeing and the people around them. Given that the occurrence of consequences was assessed for a reference period of 12 months it seems unlikely that these changes occurred over only 8 weeks.

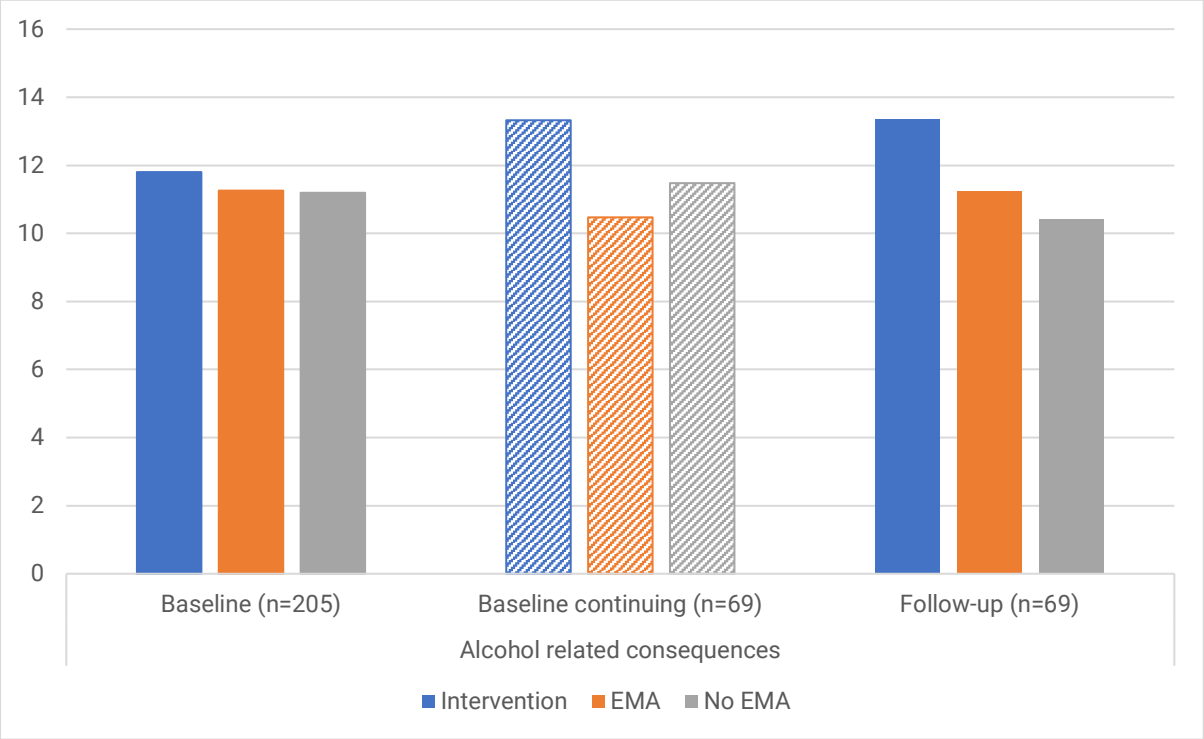


Figure 7: Number of reported alcohol-related consequences at baseline and follow-up, by treatment group.

It should be noted that participants who dropped out from the intervention group scored lower on alcohol-related consequences than those who remained in the trial. This may have had an impact on the results at follow-up. However, these differences did not obtain statistical comparisons (see Appendix Attrition Table A4).

Knowledge of Alcohol-related Harms

Figure 8 shows the means of each group regarding the knowledge of alcohol-related short-term health harms.

At follow-up only participants in the intervention group and, to some extent, those in the control group without EMA reported a slight increase in knowledge of alcohol-related short-term harm. The knowledge in the control group with EMA was the only group to report a slightly reduced knowledge of short-term harms at 8-week follow-up.

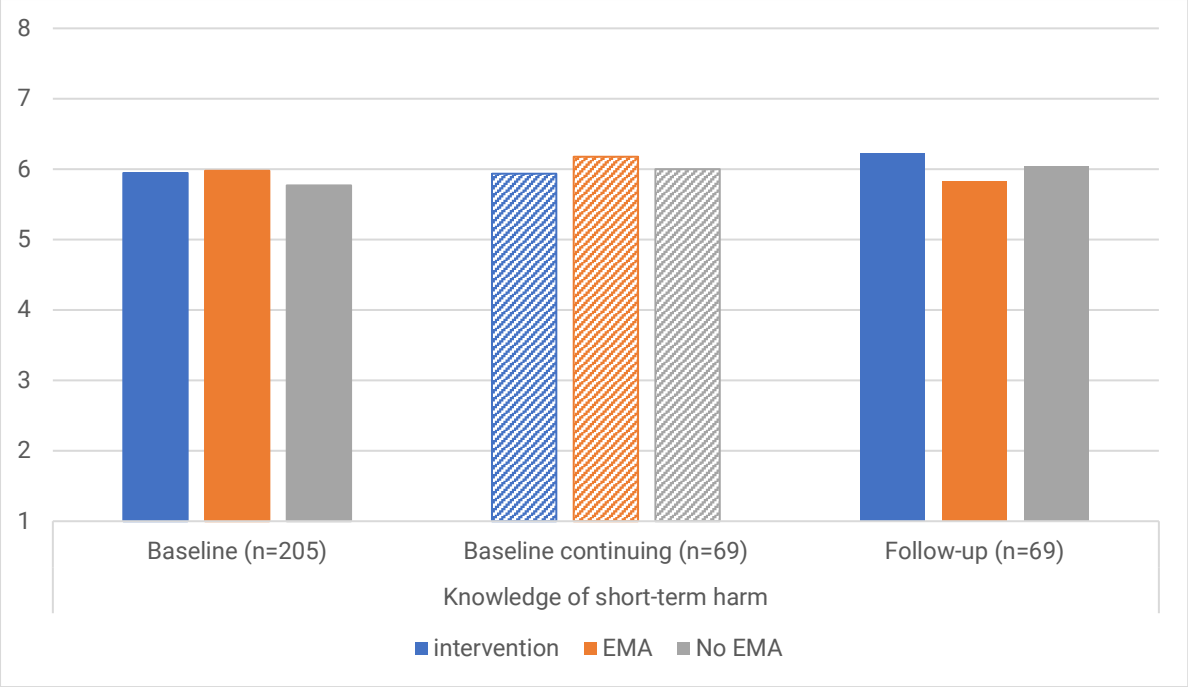


Figure 8: Knowledge of alcohol-related short-term health risks at baseline and follow-up, by treatment group.

Figure 9 shows the mean scores of each group regarding knowledge of alcohol-related long-term harms. At follow-up knowledge of long-term harms increased over the trial in all three groups while the largest increase could be found in the intervention group (2.1, 24% compared to baseline), followed by the control group with EMA (1.0, 11% compared to baseline).

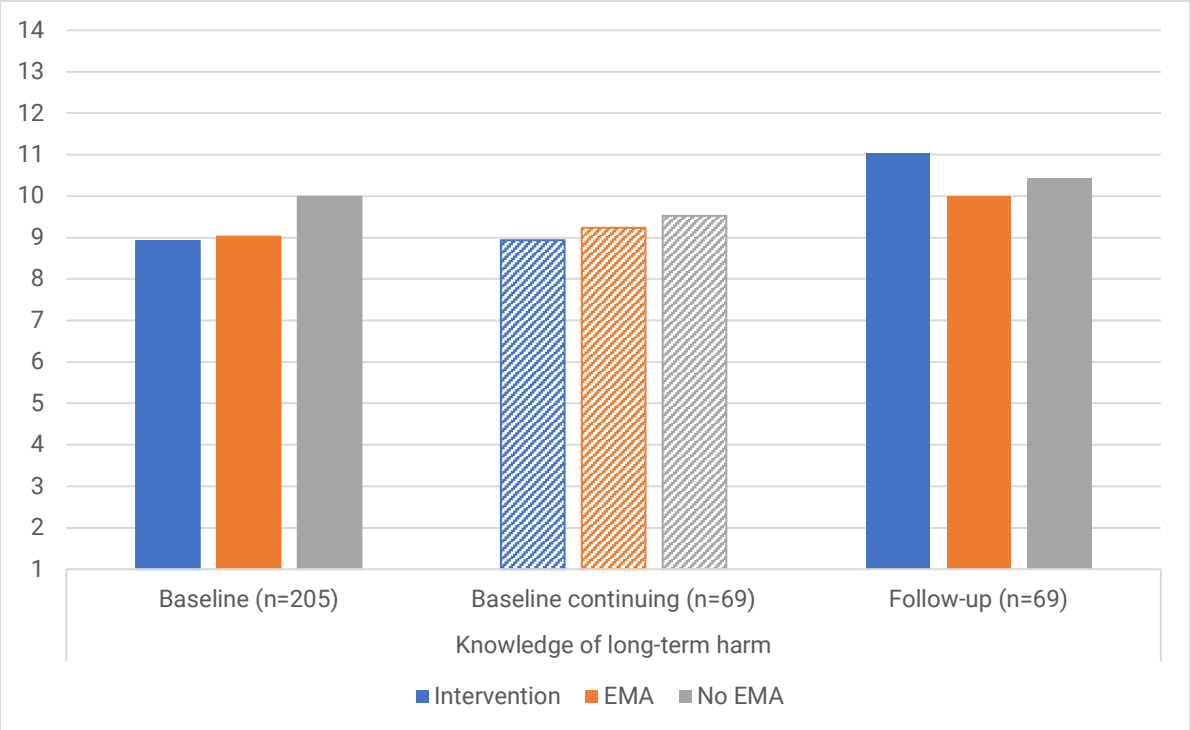


Figure 9: Knowledge of alcohol-related long-term health risks at baseline and follow-up, by treatment group.

Motivation to Reduce Alcohol Use (Readiness to Change)

Figures 10, 11 and 12 show the mean scores for each group for all three scales considered in the Readiness to Change theory; Precontemplation (Figure 10), Contemplation (Figure 11) and Action (Figure 12) respectively.

Negative values on the Precontemplation scale signify that the respondent's readiness to change their alcohol use moved beyond that step. Higher negative values signify a greater disagreement with this stage, so a higher step on the Readiness to Change scale equates to being closer to taking action in changing consumption. Among all participants who provided data at follow-up, women in the intervention group showed a more pronounced change in the level of precontemplation, indicating they were no longer in the precontemplation stage but either contemplating real change or were taking action. This indicates a higher motivation for changing alcohol use in that group at follow-up. The control group with EMA showed a slight increase on the scale while the control group without EMA remained largely unchanged.

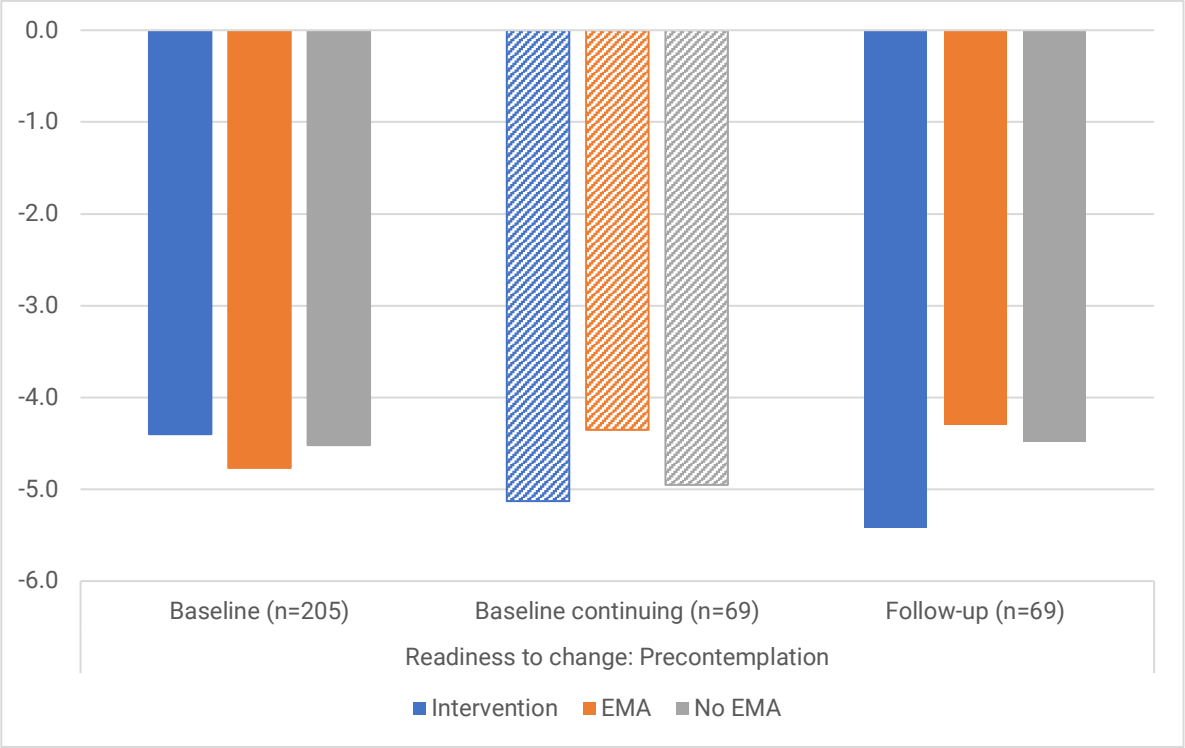


Figure 10: Readiness to change: Precontemplation at baseline and follow-up, by treatment group.

Women in the intervention group who left the trial past baseline reported more precontemplation than those who remained until follow-up. The same was found for the control group without EMA while the control group with EMA reported higher precontemplation scores when remaining in the study.

Scores on the contemplation scale (see Figure 11) were higher at follow-up for women in the intervention group while both control groups showed a small decrease for this scale. However, women in the intervention group who remained in the trial reported higher contemplation already scored at baseline.

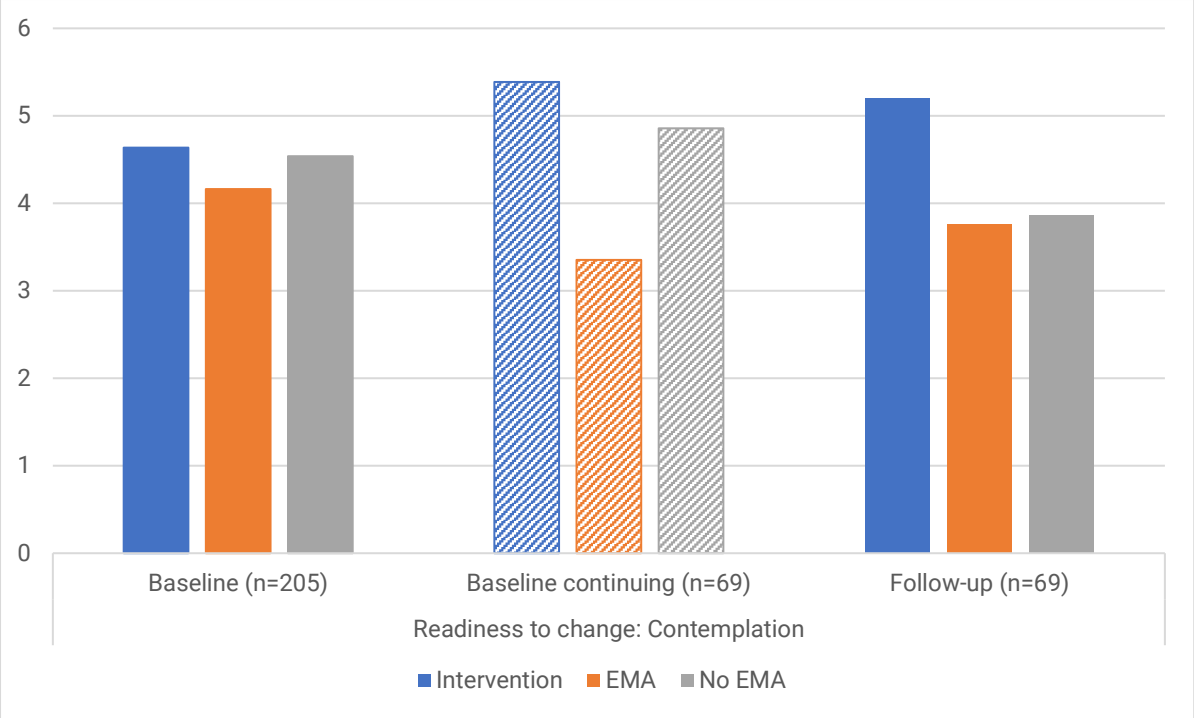


Figure 11: Readiness to change: Contemplation at baseline and follow-up, by treatment group.

Regarding the Readiness to change results for having taken 'Action' (see Figure 12) the highest increase (1.5) at follow-up was found for the intervention group, who more than doubled their baseline measure (118% increase), followed by the control group with EMA (0.4, 29%) and no change for those in the control group without EMA.

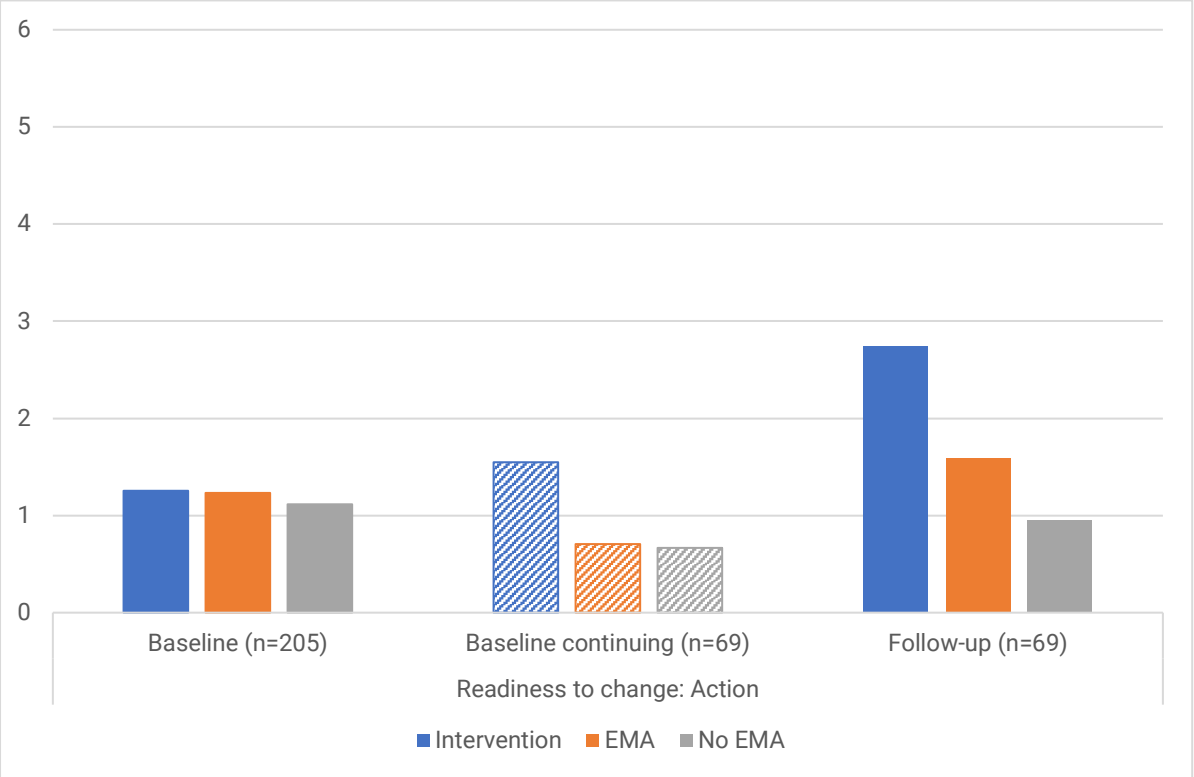


Figure 12: Readiness to change: Action at baseline and follow-up, by treatment group.

Mental Health

Figure 13 illustrates the group differences in the mean scores for mental health, where higher scores equate to poorer mental health. At follow-up women in the intervention group maintained their level of mental health, while those in the control groups reported marginal improvements in their mental health (lower values). However, considering the difference of those who remained in the trial versus those who dropped out after baseline measure, those remaining in the intervention group reported a slightly lower mental health (higher values) than those who quit the study.

It is also possible that the follow-up results could have been impacted by COVID-19 related developments and restrictions in the ACT during the duration of the trial.

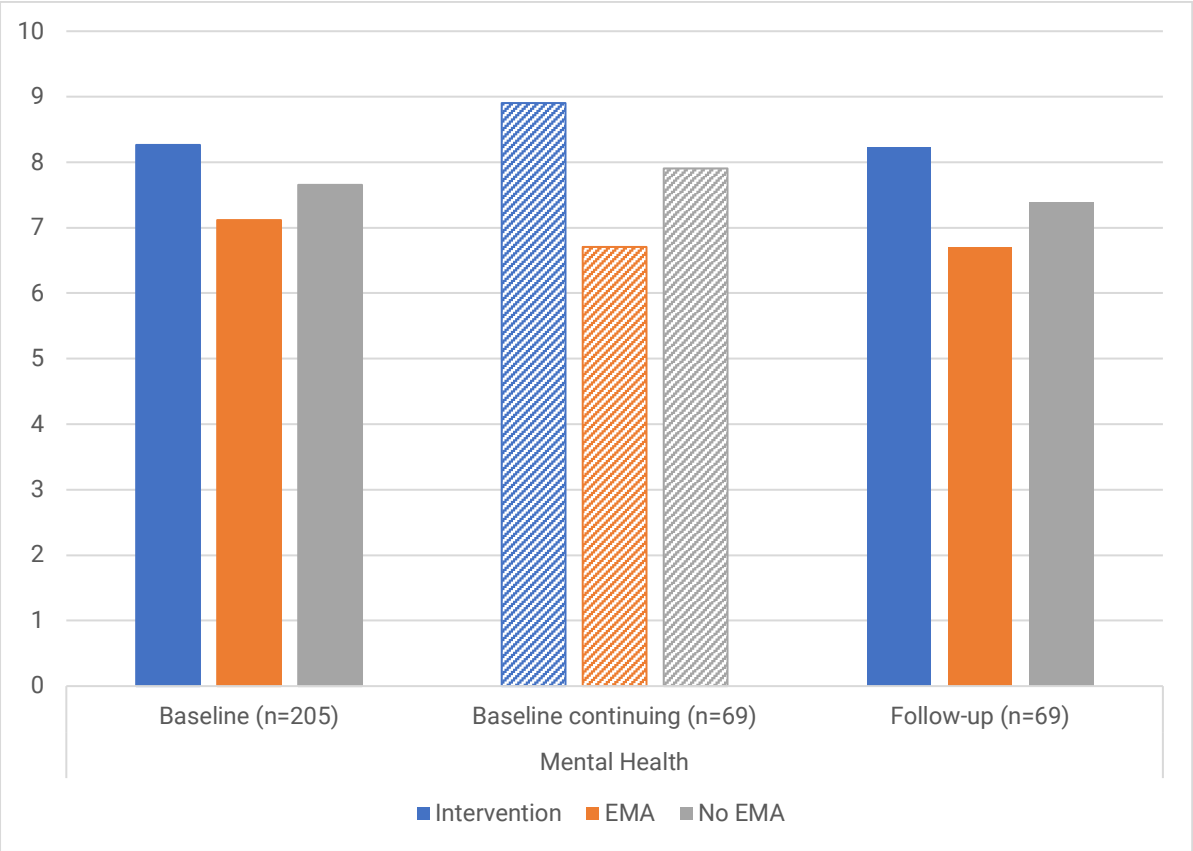


Figure 13: Mental health at baseline and follow-up, by treatment group.

Self-efficacy

At baseline there were only very minor differences between the three treatment groups (see Figure 14). At the 8-week follow-up women in the control group with EMA reported a higher level of self-efficacy compared to baseline (1.8, 8%), while for the other two groups no changes were found.

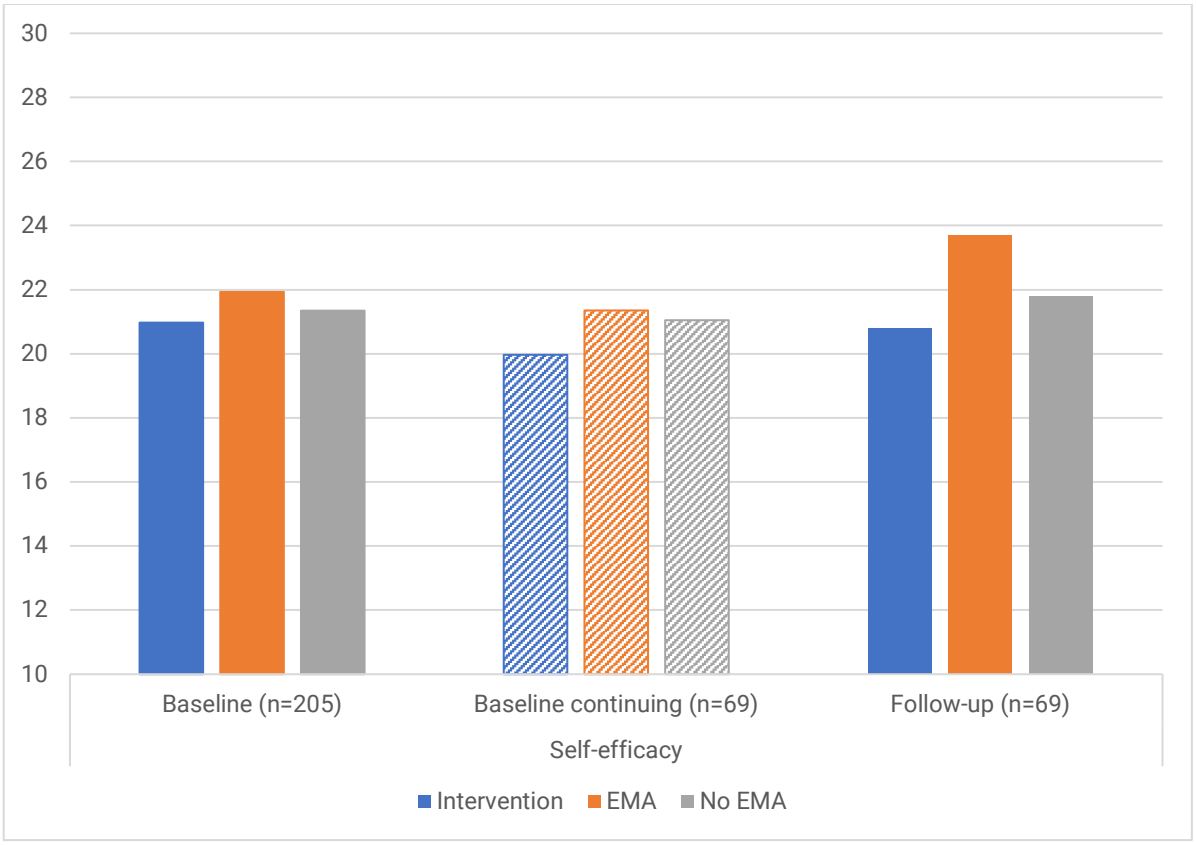


Figure 14: Self-efficacy at baseline and follow-up, by treatment group.

Discussion

Summary of Results

The results presented in this report indicate positive effects of the 'Ripple' intervention on both participating women's alcohol use and factors impacting decisions around alcohol use (secondary outcomes). Results revealed a significant reduction of over 30% in the intervention group compared to the control group for the number of standard drinks consumed in the last week. Participants reduced their consumption on this particular indicator by around 6 standard drinks across all women in the intervention group. Changes on the other consumption indicators, namely frequency of drinking in the last week, number of standard drinks and frequency of use in a typical week, did not obtain statistical significance. Despite this, reductions ranged from 24% (or about 4 standard drinks) reduction on the amount consumed in a typical week, 25% (or 1.3 days) reduction on the frequency of drinking in a typical week and 34% (or 1.5 days) reduction on the frequency of drinking in the last week prior the survey. All these reductions are within or even exceeding the objective set for the intervention regarding alcohol use:

- ✓ ***To reduce alcohol use of intervention participants 10-30 per cent.***

Regarding the Readiness to Change or motivation to alter alcohol use (Heather & Rollnick, 1993) marginal significant effects ($p<0.10$) were found for Contemplation and Action. The concept describes the stages a person moves through to reduce their alcohol use starting with Precontemplation, Contemplation and finally moving to Action. For both scales, Contemplation and Action women in the intervention group reported higher motivations to change on both scales at follow-up compared to women in the control group without EMA. As the women signing up for the trial already reported high levels on the Precontemplation and Contemplation scales the possible room for improvement was limited for these scales. However, women in the intervention group reported on average a doubling of their value on the Action scale compared to the baseline assessment (increase of 118% on the highest level of motivation to change). They also increased their values on the Contemplation scale by 0.6 points (or 12% compared to baseline). Again, the increase in the Readiness to Change Action scale, although only achieving a significance level of 10%, largely exceeded the objective set for the intervention:

- ✓ ***To increase motivation to reduce alcohol use among intervention participants by 40-50 per cent.***

A surprising finding was the significant increase of alcohol-related consequences reported by women in the intervention group at follow up compared to women in the control without EMA. This increase may be explained by the increased knowledge of alcohol-related harms in the intervention group due to the information provided by the 'Ripple' intervention. Women receiving the intervention may have had a greater likelihood to acknowledge the impact alcohol had on their health, wellbeing and the people around them and thus report higher values at follow-up. Given that the occurrence of consequences was assessed for a reference period of 12 months it seems also unlikely that these changes occurred over only 8 weeks. Further research with a larger sample and qualitative interviews with participants is needed to examine this unexpected finding.

Regarding the knowledge of alcohol-related harms, an increase (not significant) was found for long-term harms for women in the intervention group. At follow-up they reported on average two consequences more than at baseline. This increase was at least 50% larger than for any other group. No changes were found for short-term harms. Also unchanged remained the measures for self-efficacy and mental health. The follow-up measures of the latter two could have been impacted by the most recent COVID 19 related developments and restrictions in the ACT which occurred during the duration of the trial and will be discussed in the next section.

Overall, despite the limitations due to small sample size and high attrition at follow-up (see limitation section below), the authors conclude that the 'Ripple' intervention designed to address the particular circumstances around the alcohol use of middle-aged women resulted in positive changes in participating women's alcohol use and influencing factors. Women in the intervention group reported a significant reduction in their alcohol use in the last week and a significant increase in their motivation to take action and change their drinking. The authors therefore conclude that, within the restricted test power of the present RCT, 'Ripple' demonstrated its effectiveness in reducing alcohol use and increasing the motivation for change in middle-aged women in the ACT.

- ✓ ***To determine the effectiveness of an innovative digital platform to deliver alcohol harm reduction messages to reduce alcohol use to middle-aged women in the ACT.***

High rates of attrition affect the generalisability of the findings and retention rates were likely impacted by recent developments associated with COVID-19. However, as both primary and secondary outcomes indicate intervention effects in a highly under-targeted population, namely middle-aged women, a retesting in an RCT with a larger sample and less COVID-19 impacted circumstances is suggested.

Limitations

RCT Uptake and Attrition

With the rollout of the 'Ripple' intervention and the RCT the team had to face multiple difficulties. As previously mentioned, only 205 women enrolled in the trial. Initially, it was planned to enrol 3000 participants in the trial. The reduced number of participants led to a tremendous drop in testing power. Future studies should consider that middle-aged women are often engaged in multiple work and family-related obligations limiting their interest and time to engage in online interventions. The women participating in the present study reported a high level of alcohol use and high level of Readiness to Change at baseline, indicating that those participating may have contemplated action to change their alcohol use. When presented with 'Ripple' they may have simply welcomed the opportunity, while women at lower levels of consumption or Readiness to Change may not have seen the need to participate in the trial. Indication for the latter was one of the results of the focus groups conducted in the early stages of the intervention development; very few women actually considered their alcohol use problematic (Wright, Miller, Kuntsche, & Kuntsche, Submitted) or in need of change, although all welcomed an intervention for other women.

The low enrolment numbers were further accentuated by the relatively high attrition despite efforts from the team to maintain engagement with participants. The intervention group, as

well as the control group with EMA, received an SMS two times each week. For the intervention group, additional text messages were sent that included personalised feedback to reduce attrition. However, comparison of women continuing the trial and those dropping out revealed that the three groups did not differ in the level of attrition (see Appendix Table A3). Online brief interventions often suffer from high attrition (Murray et al., 2009). This general limitation may have been compounded by the length of the trial and the COVID-19 pandemic. The latter may have also served as an additional barrier to recruitment. However, the design of this study has several strengths, including the use of repeated-measures assessment using EMA. This will allow the authors (in the context of future analyses) to gain particularly detailed and rich data on participants' alcohol use over time. The twice-weekly engagement with participants via SMS providing personalised feedback would have also helped to prevent further attrition in the intervention group.

The limited number of participants, the relatively high attrition (66%) at follow-up and the use of a conservative analytical method following the intention to treat principle reduced the test power of the present RCT substantially. Consequently, although findings showed reductions in alcohol use and increases in knowledge and motivation for change, very few results obtained statistical significance. To conclude 'Ripple' has a preventive and positive impact on the alcohol use, motivation to change, alcohol-related knowledge and wellbeing of middle-aged women, the trial needs to be repeated with a larger sample.

The Context of COVID-19

The Integrated Behavioural Model (Fishbein, 2009) suggests that environmental constraints are important to consider in understanding behaviour change. It is therefore important to consider the broader context around the trial. Although the ACT has largely managed to avoid the tougher COVID-19 social restrictions of other states, COVID-19 has been linked to increasing uncertainty, anxiety and the potential for increased drinking (Rehm et al., 2020).

Before the launch of the trial, there were some concerns around trialling the intervention during the COVID-19 pandemic. This included concerns around adding extra stress or additional burden onto women's lives, the intervention becoming less of a priority, not knowing how women might engage with non-COVID-19 health-related content, the effectiveness of some of the modules (e.g., the social drinker, normative influences), and how generalisable the results would be given the unique situation.

While the ACT was able to avoid social restrictions for the duration of the trial, several outbreaks led to social distancing measures and travel restrictions that may have affected participants. This includes COVID-19 outbreaks and subsequent lockdowns in NSW on 25 June, in Victoria on 14 July, and in the ACT on 12 August. From 23 June, all ACT returning residents who had recently visited inner Sydney suburbs were placed under 14-day stay at home orders, and travellers from those areas were not allowed in the ACT. From 12 July, Victoria closed its borders with the ACT to prevent the spread of the COVID-19 Delta variant. On 12 August the ACT went into lockdown, meaning residents could only leave their house for essential reasons such as shopping for essential items, receiving medical care or short periods of outdoor exercise. While some essential workers were able to leave their homes for work, most other workers had to continue working from home. Schools and childcares were also closed in this time, meaning many parents had to supervise/home school their children. This lockdown remained through to the end of the trial. All of these factors would

have likely made trial participation a greater burden for participants and reduced drinking less of a priority. This may also partly account for the high rates of attrition we saw in the sample. Some of these concerns could not be directly addressed and should be acknowledged in the research supporting the need for a second trial using a larger sample.

Digital Intervention

There are numerous strengths in our chosen digital intervention approach. This includes being able to reach a large number of people with relative ease, adapt the platform to changing needs and priorities of the study, take repeated measures through EMA, and monitor the project continuously and remotely. Previous online interventions have also been shown to be acceptable and effective with women (Bingham et al., 2011; Riper et al., 2008; Sundström et al., 2017; A. White et al., 2010), and the codesign process would have enhanced this. However, the digital nature of the platform may have precluded some segments of the population from participating (e.g., those who may not have a strong digital literacy).

There were also several unexpected limitations, including technical issues related to the online platform and messaging system. Throughout the trial, we have worked closely with the IT consultant to problem solve technical issues as fast as possible. However, technical problems occurred outside the responsibility of the IT provider or the research team. For example, there were issues with the link to the online platform in the first two days of recruitment. Seven participants contacted the research team with issues submitting surveys, two about their data being recorded twice, two about not receiving text messages, and four with issues related to graphs showing incorrect data. These participants were given advice, their data monitored closely, and system adjustments made without requiring action from their side. However, these may have impacted participants' experiences of the intervention.

Self-report

As with most alcohol research, the reliance on self-report data can lead to reporting bias (Del Boca & Darkes, 2003). However, this is a known limitation, and it is unlikely this bias differed among the different groups or that it had a particular impact unique to middle-aged women.

Conclusions

The main objectives for this RCT were:

1. To reduce alcohol use of intervention participants 10-30 per cent.
2. To increase motivation to reduce alcohol use among intervention participants by 40-50 per cent.
3. To determine the effectiveness of an innovative digital platform to deliver alcohol harm reduction messages to reduce alcohol use to middle-aged women in the ACT.

Although only significantly so for the number of standard drinks consumed in the last week women in the intervention group reported lower alcohol use across almost all alcohol measures and thus provide support for the first objective for the 'Ripple' intervention. The only exception was heavy episodic drinking which slightly increased over the reporting period of 8 weeks. This might be linked to COVID-19 and increased uncertainty, anxiety and the potential for increased drinking (Rehm et al., 2020).

The study further found a marginally significant increase in the Readiness to change stages of Contemplation and Action when comparing women of the intervention group with those in the control group without EMA. The increased values at follow-up indicate an increase in motivation to change existing drinking behaviours and were particularly pronounced for the highest stage 'Action'. This suggests that particular strategies may be more effective among this group, such as practical self-management skills around alcohol (Heather & Rollnick, 1993). The intervention also showed an increased knowledge of alcohol-related long-term harms, although not significantly so.

However, the validity of the study is limited due to the small number of women enrolling in the RCT and a particularly high level of attrition. To come to a definite conclusion whether 'Ripple' can reduce the alcohol use of middle-aged women and increase their awareness and alcohol-related knowledge needs to be tested with a larger sample. While the intervention was initially limited to women residing in the ACT, we believe it would be useful to include more states and territories in a larger trial. Based on the current results, 'Ripple' seems to have great potential to become a very useful tool in assisting middle-aged women to reduce their alcohol use across Australia and potentially in countries with similar drinking cultures.

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Appendix

Primary outcomes										
		Baseline (n=205)		Baseline continuing (n=69)		Follow-up (n=69)		Significance tests		
		mean	SD	mean	SD	mean	SD	B	SE	p
Number of standard drinks in the last week	Intervention	16.1	11.0	15.2	12.0	9.9	10.6	-2.119	1.021	**0.039**
	Control with EMA	19.3	10.2	16.6	7.8	12.3	11.3	-2.327	1.252	*0.065*
	Control without EMA	17.1	10.6	18.2	9.8	16.6	11.6	Reference		
Number of standard drinks in a typical week	Intervention	17.1	11.7	16.4	10.9	12.9	11.5	-0.043	-0.560	0.576
	Control with EMA	19.4	10.2	15.9	7.9	14.6	10.8	-0.032	-0.411	0.681
	Control without EMA	16.3	11.2	18.3	12.1	14.1	11.8	Reference		
Frequency of heavy episodic drinking (≥4 standard drinks)	Intervention	116.2	121.4	114.7	119.5	124.8	120.3	-0.005	10.166	1.000
	Control with EMA	152.5	118.1	118.4	95.3	87.5	91.5	-21.810	12.499	*0.083*
	Control without EMA	121.6	110.2	134.1	115.7	125.0	121.2	Reference		
Drinking frequency in the last week	Intervention	4.7	2.0	4.2	2.4	3.1	2.3	-0.296	0.204	0.149
	Control with EMA	5.2	1.8	4.8	1.6	4.0	2.6	-0.170	0.251	0.500
	Control without EMA	4.8	1.8	4.9	2.0	4.1	2.2	Reference		
Drinking frequency in a typical week	Intervention	5.0	1.9	4.8	2.0	3.7	2.2	-0.056	0.199	0.777
	Control with EMA	5.2	1.8	4.8	1.6	4.5	2.0	0.159	0.244	0.515
	Control without EMA	4.8	1.9	5.0	2.0	3.8	2.3	Reference		

Appendix Table A1. Mean differences for baseline, baseline continued and follow-up (mean, SD) across primary outcomes statistical test values (linear Regression coefficients (B), Standard error (SE) and significance value (p; p<0.05 in bold, p<0.10 in italic)).

Secondary outcomes										
		Baseline (n=205)		Baseline continuing (n=69)		Follow-up (n=69)		Significance tests		
		mean	SD	mean	SD	mean	SD	B	SE	p
Alcohol-related consequences	Intervention	11.8	4.2	13.3	4.3	13.4	4.4	0.843	0.353	**0.018**
	Control with EMA	11.3	3.1	10.5	3.0	11.2	3.4	0.314	0.432	0.467
	Control without EMA	11.2	4.0	11.5	3.6	10.4	3.6	Reference		
Knowledge of short-term harm	Intervention	5.9	1.5	5.9	1.6	6.2	1.6	0.029	0.173	0.866
	Control with EMA	6.0	1.8	6.2	1.3	5.8	1.5	-0.117	0.212	0.583
	Control without EMA	5.8	2.0	6.0	1.9	6.0	2.3	Reference		
Knowledge of long-term harm	Intervention	8.9	4.0	8.9	3.3	11.0	3.9	0.324	0.391	0.408
	Control with EMA	9.0	4.6	9.2	4.1	10.0	4.4	-0.048	0.477	0.920
	Control without EMA	10.0	4.1	9.5	4.2	10.4	4.3	Reference		
Readiness to change: Precontemplation	Intervention	-4.4	2.4	-5.1	2.4	-5.4	2.3	-0.335	0.219	0.128
	Control with EMA	-4.8	2.1	-4.4	2.0	-4.3	2.6	0.117	0.269	0.664
	Control without EMA	-4.5	2.7	-5.0	2.7	-4.5	2.3	Reference		
Readiness to change: Contemplation	Intervention	4.6	2.9	5.4	2.4	5.2	2.6	0.423	0.254	*0.098*
	Control with EMA	4.2	2.8	3.4	3.5	3.8	2.7	0.060	0.312	0.847
	Control without EMA	4.5	2.9	4.9	2.7	3.9	3.3	Reference		
Readiness to change: Action	Intervention	1.3	2.4	1.5	2.4	2.7	2.1	0.423	0.254	*0.098*
	Control with EMA	1.2	2.5	0.7	2.8	1.6	2.5	0.060	0.312	0.847
	Control without EMA	1.1	2.1	0.7	2.2	1.0	2.9	Reference		

Appendix Table A2. Mean differences for baseline, baseline continued and follow-up (mean, SD) across primary outcomes statistical test values (linear Regression coefficients (B), Standard error (SE) and significance value (p; p<0.05 in bold, p<0.10 in italic)).

Secondary outcomes										
		Baseline (n=205)		**Baseline continuing (n=69)**		**Follow-up (n=69)**		**Significance tests**		
		mean	**SD**	**mean**	**SD**	**mean**	**SD**	**B**	**SE**	**p**
Mental Health	Intervention	8.3	3.8	8.9	4.1	8.2	4.6	0.090	0.361	0.803
	Control with EMA	7.1	3.4	6.7	3.0	6.7	3.6	-0.112	0.442	0.801
	Control without EMA	7.7	3.7	7.9	4.0	7.4	3.8	Reference		
Self-efficacy	Intervention	21.0	4.1	20.0	4.2	20.8	5.1	-0.165	0.425	0.699
	Control with EMA	21.9	3.9	21.4	3.6	23.7	4.5	0.568	0.521	0.277
	Control without EMA	21.3	4.9	21.0	5.7	21.8	4.8	Reference		

Appendix Table A2. Mean differences for baseline, baseline continued and follow-up (mean, SD) across primary outcomes statistical test values (linear Regression coefficients (B), Standard error (SE) and significance value (p; p<0.05 in bold, p<0.10 in italic)), continued.

	Baseline assessment	Participants who dropped out (n=136)	Participants who remained (n=69)	Chi-Square	df	p
Age of the respondent	44-49	19.9%	20.3%	2.227	4	0.694
	50-54	27.2%	18.8%			
	55-59	22.8%	23.2%			
	60-64	16.2%	21.7%			
	65+	14.0%	15.9%			
Highest level of education	no secondary education	0.7%	1.4%	.281	4	0.991
	completed secondary	8.1%	8.7%			
	Diploma/TAFE	16.2%	15.9%			
	Bachelor	40.4%	39.1%			
	Postgraduate	34.6%	34.8%			
Employment situation	unable to work	1.5%	1.4%	2.386	7	0.935
	retired	8.1%	11.6%			
	unemployed	0.7%	1.4%			
	home duties	2.9%	4.3%			
	self-employed	6.6%	8.7%			
	casual	3.7%	2.9%			
	part-time	17.6%	20.3%			
	full time	58.8%	49.3%			
Dependent children	no	42.6%	49.3%	.813	1	0.367
	yes	57.4%	50.7%			
Marital status	single	6.6%	10.1%	1.969	4	0.741
	widowed	1.5%	2.9%			
	divorced	16.2%	17.4%			
	separated	7.4%	4.3%			
	married	68.4%	65.2%			
Intervention group	Intervention	58.1%	44.9%	3.196	2	0.202
	Control with EMA	19.1%	24.6%			
	Control without EMA	22.8%	30.4%			

Appendix Table A3. Comparison of baseline measures and significance testing (Chi-Square difference test, degrees of freedom (df) and significance level (p) based on RCT retention (continuing sampling vs dropouts).

	Baseline assessment	Participants who dropped out (n=136)	Participants who remained (n=69)	t-test	df	p
Alcohol use	Number of standard drinks in a typical week	16.9	17.6	-0.541	203	0.589
	Number of standard drinks in the last week	16.4	17.3	-0.452	203	0.652
	Frequency of drinking in a typical week	5.1	4.9	-0.726	203	0.469
	Frequency of drinking in the last week	5.0	4.5	-1.594	203	0.113
	Frequency of heavy episodic drinking (4 standard drinks or more)	127.1	121.5	-0.317	203	0.752
Alcohol related consequences		11.3	12.1	1.362	203	0.175
Alcohol related knowledge of harm	Short-term harm	5.9	6.0	0.632	203	0.528
	Long-term harm	9.2	9.2	-0.052	203	0.959
Readiness to change	Pre-contemplation	-4.9	-4.3	-1.585	203	0.114
	Contemplation	4.7	4.4	0.753	203	0.453
	Action	1.1	1.3	-0.617	203	0.538
Mental health		8.1	7.8	0.519	203	0.604
Self-efficacy		21.6	20.6	-1.511	203	0.132

Appendix Table A4. Comparison of baseline measures and significance testing (t-test, degrees of freedom (df) and significance level (p) based on RCT retention (continuing sampling vs dropouts).