

**Efficacy of brief intervention for alcohol consumption during pregnancy in Argentinean women: a randomized controlled trial**

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Manuscripts

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4 **Efficacy of brief intervention for alcohol consumption during pregnancy in Argentinean**  
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6 **women: a randomized controlled trial**  
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8  
9 **Abstract**

10  
11 **Introduction:** Although Brief Intervention (BI) has proven to reduce alcohol  
12 consumption during pregnancy in high income countries, there is no evidence from the  
13 Southern Cone of America. Thus, we conducted a study to assess BI efficacy among  
14 Argentinean pregnant women. **Method and Materials:** We collected data on pregnant  
15 women receiving prenatal care at the public health system in Mar del Plata, Argentina.  
16 Women with less than 26 weeks of gestation (n = 486) were randomized to brief advice (BA)  
17 or BI. Three months later they were re-assessed; women with more than 26 weeks of gestation  
18 constituted a screening only control group (SC) (n=154). Self-reported quantity and frequency  
19 of alcohol consumption, frequency of binge drinking, and related problems after three months  
20 were used as outcomes. We performed generalized estimating equations and clinical  
21 significance analyses. **Also, we** obtained newborn health indicators from the city's health  
22 system database to use as objective outcomes. Women who did not participate in any of the  
23 three former conditions were randomly selected to constitute a non-screening control group  
24 (NSC) (n=150). We compared objective outcomes among BI, BA, and NSC groups using the  
25 Wilcoxon rank test. **Results:** In comparison with SC, BI and BA reduced alcohol  
26 consumption, without differences between the latter two. Newborns of women who received  
27 BI and BA had better health indicators compared with the NSC group. **Conclusions:**  
28 performing either a BI or BA reduces alcohol consumption among Argentinean pregnant  
29 women and might lead to healthier newborns.  
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54 **Keywords:** alcohol, pregnant women, brief intervention, Argentina  
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4 **Efficacy of brief intervention for alcohol drinking during pregnancy in Argentinean**  
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6 **women: a randomized controlled trial**  
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9 Preventing prenatal alcohol exposure poses a major challenge to public health across  
10 the world (World Health Organization [WHO], 2014). Alcohol use during pregnancy can lead  
11 to a series of alcohol-related problems for the pregnant woman and the fetus (Oei, 2020).  
12 Those consequences are a hundred percent preventable if no alcohol is consumed during  
13 pregnancy (Charness et al., 2016). Among them, miscarriage (Henriksen et al., 2004), low  
14 birth weight, preterm birth (Patra et al., 2011), and a wide range of physical, cognitive,  
15 neurological, and behavioral characteristics encompassed in Fetal Alcohol Spectrum Disorder  
16 (FASD) (Oei, 2020). Also, recent studies detected functional biomarkers among newborns of  
17 mothers who consumed alcohol during pregnancy. For example, Anunziata et al. (2020)  
18 found that newborns of mothers who drank showed respiratory depression and facial reactions  
19 when the babies were olfactory stimulated with ethanol.  
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34 The prevalence of alcohol consumption during pregnancy varies across countries.  
35 Among North American countries, it is estimated that between 10 to 15 % of pregnant women  
36 drink (Popova et al., 2017), while countries from South America show a higher prevalence.  
37 For example, 75% of the pregnant women in Argentina reported consuming alcohol during  
38 pregnancy (Lopez et al., 2015), while 63% reported doing so in Uruguay (Míguez et al., 2009)  
39 and 57% in Chile (Aros et al., 2006). Furthermore, prenatal drinking constitutes an even more  
40 significant challenge in Latin-American countries than others, where the lack of government-  
41 specific guidelines makes addressing alcohol consumption in pregnant women more difficult  
42 (WHO, 2014).  
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54 Brief Intervention (BI) is the most commonly used tool to reduce alcohol consumption  
55 among pregnant women, and WHO has recommended BI as a cost-effective strategy (WHO,  
56 2014). However, efficacy studies are scarce (Erng et al., 2020). In addition, evidence of  
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4 efficacy is mainly limited to high-income countries, and it is necessary to develop cultural  
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6 adaptations of BI in low and middle-income countries (Lichtenberger et al., 2016),  
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8 considering that countries like Argentina, for example, has very different pattern of  
9  
10 consumption than that in other countries where this research has been based. Argentina has a  
11  
12 Mediterranean-style drinking culture characterized by high per capita consumption (Savic et  
13  
14 al., 2016) and the integration of alcohol into social life, which is highly acceptable and  
15  
16 encourages consumption. A recent study shows that Argentinean women who drink during  
17  
18 pregnancy perceived more acceptability from their family and friends than those who  
19  
20 abstained (Lichtenberger, et al 2020).  
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25 BI is a time-limited motivational intervention. It has been defined as *opportunistic*  
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27 (Babor et al., 2007), as its recipients have not yet reported an alcohol problem, but are  
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29 identified as consuming in ways that involve a certain risk. BI can be performed by  
30  
31 professionals from different disciplines or by non-specialized personnel after training (Babor  
32  
33 et al., 2017). Most effective BIs usually include 1) feedback aimed at increasing awareness of  
34  
35 the negative consequences of alcohol consumption, 2) advice focused on identifying risky  
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37 situations and promoting actions aimed at reducing consumption, and 3) assistance in  
38  
39 formulating goals for reducing alcohol consumption (Cremonte et al., 2013). With pregnant  
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41 women BI aims to identify drinking and motivate women to achieve abstinence (Graves et al.,  
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43 2020).  
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48 Even though many women stop or reduce their alcohol consumption during pregnancy  
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50 for different reasons, such as being concerned for the wellbeing of their babies or for religious  
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52 beliefs (Martinelli et al., 2019), pregnant or reproductive-age women who receive BI have  
53  
54 been found to achieve and maintain abstinence more successfully than those from control  
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56 groups (Martino et al., 2018; Nilsen, 2009). However, reductions in drinking have also been  
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58 detected among control groups (Marais et al., 2011; Nilsen, 2009; Sheenan et al., 2014). The  
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4 effect on outcomes among control groups is a recognized phenomenon in the BI field,  
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6 explained mainly by regression to the mean or instrumental bias such as screening reactivity  
7  
8 (Gual et al., 2016). For this reason, and to help explain conflicting evidence, control groups  
9  
10 that do not receive any screening have been recently recommended (Jecks et al., 2018). Also  
11  
12 suggested is the use of objective outcome measures along with the traditional self-reported  
13  
14 consumption instruments (Glass et al., 2017). **Pregnancy studies carried out** in the US have  
15  
16 employed newborn health indicators as objective outcome data, suggesting that BI has a  
17  
18 positive impact on newborn weight and length, while decreasing fetal death and increasing  
19  
20 full-term births (Armstrong et al., 2009; O'Connor & Whaley, 2007; Tzilos et al., 2011).  
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25 We conducted **a study** to assess BI efficacy among Argentinean pregnant women.  
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27 Toward this aim, we used a subjective outcome measure (self-reported alcohol consumption  
28  
29 and related problems) and an objective outcome measure (newborns health indicators). We  
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31 hypothesized that BI would be effective in a cultural context where drinking during  
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33 pregnancy is higher than that found in studies from other countries, while addressing some of  
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35 the previous concerns raised such as the lack of non-screening control groups and the use of  
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37 non-objective outcome measures.  
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## 41 **Method**

### 42 ***Self-report of alcohol consumption and related problems***

#### 43 ***Participants and Procedure***

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46 The study sample was all pregnant women receiving prenatal care in the public health  
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48 system in Mar del Plata, Argentina, from April to September 2016. 893 women were invited  
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50 to participate, of which 8 refused to take part in the study and 3 were excluded as they were in  
51  
52 alcohol or other drug treatment. The remaining participants were screened for their alcohol  
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54 consumption with the Alcohol Use Disorders Identification Test (AUDIT) (Babor et al.,  
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56 2001): 219 women were excluded from the sample as they did not report any alcohol  
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4 consumption during the last 12 months and 23 women were referred to specialized treatment  
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6 for presenting indicators of an Alcohol Use Disorder (AUD). A total of 640 women met the  
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8 inclusion criteria and were given full and detailed information about the study in a written  
9  
10 information sheet. Parents' or legal guardians' representation was not required, as no  
11  
12 participant was under 13 years of age, the legal age to consent treatment in Argentina  
13  
14 (National Law 26.529 about Patient Rights, 2009). If a participant showed a low literacy  
15  
16 level, the researcher read the information sheet to the patient. Women who gave their verbal  
17  
18 informed consent were given the information sheet and screened for alcohol consumption  
19  
20 through a self-report questionnaire (described in the measure section). The procedure and  
21  
22 project materials were assessed and approved by the City Mental Health Department and an  
23  
24 Ethical Committee. The trial was not pre-registered in a public repository. The registration of  
25  
26 trials is not an extended practice for psychological interventions in Argentina. Also,  
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28 institutions that finance as well as those where the studies are carried out, do not require  
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30 registration.  
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36 *Inclusion criteria* were a) being currently pregnant, b) informed consent after reading  
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38 or listening to the information sheet, and c) consuming alcohol in the past 12 months.  
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41 *Exclusion criteria* were a) no alcohol consumption last 12 months, b) being under  
42  
43 treatment for alcohol or other substances use, c) being identified through the AUDIT as  
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45 presenting alcohol use disorders (AUD) (these participants were encouraged to seek  
46  
47 specialized treatment) and d) being cognitively unable to understand the questionnaire.  
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50 Although studies of the efficacy of BI typically include only women who drink during  
51  
52 pregnancy, or those who drink at high-risk levels, we decided to also include those who  
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54 reported abstinence since recognition of pregnancy but did report drinking in the last year for  
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56 two reasons. First, some women may not have consumed alcohol by the time of the interview  
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58 because of reasons other than protecting themselves and their babies, for example, because  
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4 they felt nauseated during the first months of pregnancy or they had not had the social  
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6 opportunity to drink. Second, since alcohol consumption during pregnancy is normalized in  
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8 the region, some women may not have had information about its negative consequences and  
9  
10 thus present an excellent opportunity for encouraging the maintenance of abstinence.  
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### 17 *Brief advice (BA) and brief intervention (BI) groups*

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19 Women up to 26 weeks of gestation were randomized into either the BA or BI group.  
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21 The 26<sup>th</sup> week of gestation was used as a cut-off point to administer follow-up assessments 12  
22  
23 weeks later for those in the BA or BI conditions, while women were still pregnant (a normal  
24  
25 pregnancy lasts between 38 to 42 weeks).  
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29 We invited women to participate when they were in the prenatal health care waiting  
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31 room. The professionally trained study personnel who recruited the participants also provided  
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33 screening and delivered the BI or BA. Also, participants were blinded to the condition they  
34  
35 received. We began randomization raffling the first participant to BI or BA and continued  
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37 with a one-by-one procedure. For example, if the first participant raffled BI, the next received  
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39 BA, and so on. If a participant refused to continue participating, the data were regarded as  
40  
41 lost. All participants received clear advice on alcohol abstinence (about 5 minutes). After  
42  
43 screening, BA participants received a brochure with information on the risks of prenatal  
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45 alcohol exposure, while BI participants received the BI interview (about 15 minutes). If a  
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47 participant showed a low literacy level, the researcher read the whole brochure.  
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52 Participants in the BI and BA were re-contacted and assessed by phone within three  
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54 months of the first interview. Telephone communication was attempted five times over two  
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56 weeks. During the telephone interview, quantity, and frequency of consumption along with  
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58 the AUDIT for the last three months were assessed. To minimize potential biases those  
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4 conducting the telephone interviews were blind as to the participant's condition. The three-  
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6 month re-contact rate was 56%, with no difference between the BI and BA condition.  
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### 8 9 *Screening Control Group*

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11 Women with more than 26 weeks of gestation were included as a *screening only*  
12  
13 *control group* (SC). Since women in this group did not receive any kind of intervention, their  
14  
15 data reflect alcohol consumption at a more advanced stage of the pregnancy for those who  
16  
17 received regular care in primary health centers. They were assessed only once about alcohol  
18  
19 consumption before and after pregnancy recognition (see *measures* for more information). At  
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21 the time of the assessment they were around 6-7 months of pregnancy. Data from SC  
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23 assessment, and the BI and BA follow-up could be compared because the period of pregnancy  
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25 between them matches.  
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29 For ethical reasons SC participants received the same brochure as BA participants and,  
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31 therefore, could not be assessed in the newborn study.  
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34 Figure 1 shows a flowchart with groups' distribution and the studies' designs.  
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36 [Figure 1 about here]  
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## 41 ***Measures***

### 42 43 *Screening measures*

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47 *Alcohol consumption in the previous 12 months:* Women were asked about the frequency of  
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49 alcohol consumption in the past 12 months before the interview. Those women who reported  
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51 even one drink during this time were included.  
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55 *Alcohol Use Disorder:* The Alcohol Use Disorder Identification Test (AUDIT) (Babor et al.,  
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57 2001) was used to assess consumption and related problems for the period following  
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59 pregnancy recognition. Women who scored  $\geq 4$  were considered as having a probable AUD  
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4 and excluded from the study. The AUDIT has demonstrated adequate psychometric properties  
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6 in pregnant Argentinean women,  $\alpha = 0.93$ , Sensitivity = 87%, Specificity = 86% (López et al.,  
7  
8 2017).  
9

### 10 11 *Baseline Assessment*

12  
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15 For BI and BA groups baseline assessment included:

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18 *Basic demographic information:* age, marital status, educational level, occupation,  
19  
20 gestational weeks, number of children, and socioeconomic status.  
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24 *Quantity of consumption before and after pregnancy recognition:* Quantity of consumption  
25  
26 was estimated in standard units (SU, 1 unit = 11g) of absolute alcohol consumed in a typical  
27  
28 day of drinking (Cremonte et al., 2010). Specifically, for the quantity of consumption before  
29  
30 pregnancy recognition, the question was: *During the past twelve months, how many drinks did*  
31  
32 *you have on a typical day that you drink?* In the case of the quantity of consumption after  
33  
34 pregnancy recognition, the question was: *Since you found out you are pregnant, how many*  
35  
36 *drinks do you have on a typical day that you drink?*  
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41 *Frequency of consumption before and after pregnancy recognition:* Frequency of  
42  
43 consumption was estimated by asking the patient how often she drank alcohol in the past 12  
44  
45 months and after pregnancy recognition, elicited from the following response categories:  
46  
47 *Never, Once a month, 2-4 times a month, 2-3 times a week, and 4 or more times a week.*  
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50  
51 *Frequency of Binge drinking before and after pregnancy recognition:* Binge drinking was  
52  
53 considered consuming 4 or more drinks on an occasion in the past 12 months and after  
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55 pregnancy recognition. Response categories were: *Never, Less than once a month, Monthly,*  
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57 *Weekly, and Daily.*  
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4 *Alcohol-related problems before and after pregnancy recognition: Alcohol-related problems*  
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6 were assessed from the last 7 questions of the AUDIT as a quantitative variable on a scale of  
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8 0 to 28 points. These questions include information on how often in the past 12 months and  
9  
10 after pregnancy recognition participants had experienced one of the following problems  
11  
12 related to alcohol consumption: not being able to stop drink once they had started, failing to  
13  
14 do what was expected from them, needing a drink in the morning, feeling guilty after  
15  
16 drinking, being unable to remember what happened during drinking, injuring themselves or  
17  
18 others because of their drinking and having received a suggestion to cut down drinking by  
19  
20 family, friends, doctors or others. Response categories were: *Never, Less than once a month,*  
21  
22 *Monthly, Weekly, and Daily.*  
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28 For the SC group, the baseline assessment included *Basic demographic information, Quantity*  
29  
30 *of consumption, Frequency of consumption, Frequency of Binge drinking and Alcohol-related*  
31  
32 *problems before pregnancy recognition*, using the same measures described for BI and BA.  
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#### 35 *Follow-Up Assessment*

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39 For the BI and BA groups the follow-up included *Quantity and Frequency of alcohol*  
40  
41 *consumption, Frequency of binge drinking, and Alcohol-related problems during the past 3*  
42  
43 *months* using the same measures described for the baseline assessment.  
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#### 46 *Late pregnancy evaluation*

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50 There was no follow-up assessment for the SC group. Instead, participants received a late  
51  
52 pregnancy evaluation about *Quantity and Frequency of alcohol consumption, Binge drinking*  
53  
54 *frequency, and Alcohol-related problems after pregnancy recognition* when they were more  
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56 than 26 weeks of pregnancy, using the same measures described for the baseline assessment.  
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59 As noted above, since the SC group was assessed when they were around 6-7 months  
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4 pregnant, their evaluation comprised the same pregnancy period as the follow-up assessment  
5  
6 of the BI and BA groups. Also, SC participants represent alcohol consumption among women  
7  
8 who received regular care at the health centers.  
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### 10 11 12 *Interventions*

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15 *Brief Interventions (BI):* For those women who reported drinking after pregnancy recognition,  
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17 the BI aim was to encourage abstinence, while for those who did not drink after pregnancy  
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19 recognition but reported consumption in the previous 12 months, the BI aim was to maintain  
20  
21 abstinence.  
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24  
25 The BI was a brief motivational interview (Miller & Rollnick, 2012) with a duration of  
26  
27 15 minutes. The active ingredients of efficacy reported in Gaume et al. (2014) were included.  
28  
29 We provided: feedback on screening results along with clear advice of abstinence,  
30  
31 information on the consequences of prenatal alcohol exposure, a menu of strategies and  
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33 options to achieve abstinence, and reasons for ceasing consumption. At the end of BI, self-  
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35 efficacy was encouraged. Also, we gave our contact information (e-mail) in case they need  
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37 more information or have questions.  
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42 *Brief advice (BA):* BA patients were given clear advice on alcohol abstinence which lasted  
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44 about 5 minutes and given a brochure containing advice on abstinence and information about  
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46 the consequences of prenatal alcohol exposure.  
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50 All BI and BA interviews were performed in the city health centers' in areas of the  
51  
52 waiting room, which afforded sufficient privacy. Six professional psychologists, trained in  
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54 recognizing alcohol consumption problems, providing a BI, and applying the study protocol,  
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56 carried out the interviews. Training consisted of eight theoretical hours and one week of  
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4 practice where the psychologist provided the intervention accompanied by a supervisor (an  
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6 investigator of the project).  
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10 *Preliminary analyses*  
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13 To determine if the randomization procedure had produced equivalent groups, we  
14  
15 performed  $X^2$  and Kruskal-Wallis tests on participants' characteristics. Table 1 summarizes  
16  
17 the descriptive data by condition. The three groups only differed in the number of children;  
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19 therefore it was included as a covariate in the models.  
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23 [Table 1 about here]  
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32 *Data analysis*  
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34 First, we performed descriptive analyses on the three groups for the outcome  
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36 variables: quantity and frequency of alcohol consumption, frequency of binge drinking, and  
37  
38 alcohol-related problems. To estimate the efficacy of BI, we used inferential statistics to  
39  
40 compare 1) BI vs BA accounting for outcomes before and after pregnancy recognition and  
41  
42 follow-up; 2) BI and BA vs SC for outcomes before pregnancy recognition and follow-up (for  
43  
44 BI and BA) or late pregnancy evaluation (for SC). We used generalized estimating equations  
45  
46 (GEE), examining the effect of BI and BA as well as change over time. An interaction term  
47  
48 intervention\*time was included, as well as the number of children, as a control. We did not  
49  
50 perform these and subsequent analyses on alcohol-related problems, as no variability was  
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52 found across groups at the follow-up (see Table 2). For quantity of alcohol consumption  
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54 negative binomial Poisson regressions were performed, while for frequency of drinking and  
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4 frequency of binge drinking ordinal regressions were modeled. We used R 4.0.3 and SPSS  
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6 version 15.  
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10 As this type of study generally involves changes that might not reach statistical  
11  
12 significance but may be clinically significant, relative risk (RR), absolute risk reduction  
13  
14 (ARR), and number needed to treat (NNT) were estimated between the BI and BA conditions.  
15  
16 We computed the intervention as non-effective when women increased or maintained their  
17  
18 scores on outcomes measures between the assessment after pregnancy recognition and the  
19  
20 three-month follow-up assessment after BI or BA. In addition, since we used an intention-to-  
21  
22 treat approach, those interventions that were performed but follow-up could not be achieved  
23  
24 were also considered as non-effective. Because it is thought that un-reachable patients have  
25  
26 worse outcomes, this method reduces biases in assessing the efficacy of the intervention,  
27  
28 providing more conservative estimates while treating the participants according to the  
29  
30 randomization (McCoy, 2017).  
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### 35 36 ***Objective newborn health indicators***

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38 Newborn health indicators (NHI) were obtained from the city's health system database  
39  
40 containing information about all births between January and March 2017. They included birth  
41  
42 weight in kilograms and gestational age at birth in weeks, **outcomes that are affected by**  
43  
44 **alcohol consumption during pregnancy (Patra et al., 2011)**. We were able to identify 30% of  
45  
46 those women in the BI and BA groups by their ID.  
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50 From the same database we also obtained the NHI from newborns whose mothers did  
51  
52 not participate in any of the previous groups (BI, BA or SC, see Figure 1). The newborn non-  
53  
54 screened control (NSC) group participants ( $n=150$ ) were randomly selected from the data base  
55  
56 among those women who had given birth during March 2017 ( $n = 462$ ). This date was chosen  
57  
58 to ensure every woman from the BI, BA and SC groups had already delivered, and therefore  
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4 the data used for NSC group were from women who received no intervention other than the  
5  
6 regular health care.  
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#### 8 *Data analysis*

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11 Newborns health indicators among BI, BA, and NSC groups were described and  
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13 compared against each group using the Wilcoxon rank test and Cliff's delta as a measure of  
14  
15 effect size. For analyses, the R Project for Statistical Computing was used in version 4.0.3.  
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## 20 **Results**

### 21 ***Self-report of alcohol consumption and related problems***

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27 The descriptive statistics of outcome variables (quantity and frequency of alcohol  
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29 consumption, frequency of binge drinking, and alcohol-related problems) are presented in Table  
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31 2. The proportion of women who stopped drinking was increasingly higher in each period (BPR,  
32  
33 APR and follow-up). Almost none of the pregnant women binged during pregnancy, and none  
34  
35 presented alcohol-related problems. The quantity of alcohol consumption decreased by more  
36  
37 than two standard units after pregnancy recognition for the BI and BA conditions and more than  
38  
39 one standard unit for the SC condition. The greatest reduction in alcohol-related problems was  
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41 in the BI group.  
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46 [Table 2 about here]

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49 The GEE models are presented in Table 3. When comparing BI and BA conditions, the  
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51 only significant predictor was time for almost all the outcomes. That is, regardless of the  
52  
53 condition, there was a reduction of quantity and frequency of alcohol consumption and  
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55 frequency of binge drinking due to the passage of time during pregnancy. The number of  
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57 children also predicted a reduction in frequency of binge drinking during pregnancy. In contrast,  
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4 when comparing BI and BA conditions to SC, almost all the alcohol consumption outcomes  
5 were predicted by condition, time, interaction intervention\*time, and the number of children.  
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7 This indicates that women who received either BI or BA had greater decreases in quantity and  
8  
9 frequency of alcohol consumption, as well as in frequency of binge drinking at the follow-up  
10  
11 assessment. The only non-significant interaction was between time\*BI intervention.  
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16 [Table 3 about here]  
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20 The Relative risk (RR), absolute risk reduction (ARR), and number needed to treat  
21 (NNT) results are presented in Table 4. The results of RR show no differences between BI  
22 and BA. However, the ARR indicated a small but favorable effect of BI against BA,  
23 especially for quantity and frequency outcomes. That is, pregnant women who received BI  
24 had a 4% reduction in the likelihood of increasing the quantity of drinks consumed per  
25 occasion and a 5% reduction in the likelihood of increasing the frequency of consumption,  
26 compared with the BA group. Also, according to NNT analysis, to benefit one pregnant  
27 woman it is necessary to treat 22 to reduce the quantity of consumption and 20 to reduce the  
28 frequency of consumption with BI instead of BA. For binge drinking and alcohol-related  
29 problems, NNT was more than 50 (Table 4).  
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43 [Table 4 about here]  
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#### 46 ***Objective newborn health indicators***

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49 According to descriptive analyses (not shown in tables), the average birth weight by  
50 group was  $M=3349.81$  ( $DS=542.428$ ) for BI,  $M=3387.29$  ( $SD=551.410$ ) for BA, and  
51  $M=3181.25$  ( $SD=592.652$ ) for non-screened controls (NSC). Moreover, the average  
52 gestational age by group was  $M=38.86$  ( $SD=1.43$ ) for BI,  $M=38$  ( $SD=1.24$ ) for BA, and  
53  $M=37.85$  ( $SD=3.59$ ) for NSC. Statistically significant differences in birth weight and  
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4 gestational age at birth were found between the BI and NSC groups and between the BA and  
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6 NSC groups (see Table 5). No statistically significant differences in birth weight and  
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8 gestational age at birth were found between newborns of women in the BI group compared to  
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10 those in the BA group.  
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14 [Table 5 about here]  
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## 19 20 Discussion

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22 **Our study aimed to determine** BI efficacy in promoting alcohol abstinence during  
23 pregnancy or maintaining it among those who did not consume alcohol after the pregnancy  
24 among Argentinean women. **We evaluated** self-reported alcohol consumption (quantity and  
25 frequency of alcohol consumption and frequency of binge drinking) and alcohol-related  
26 problems three months following the intervention. We also evaluated the **objective outcomes**  
27 **of newborn health indicators (weight and gestational age at birth).**  
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36 The results indicate that women in the BI and BA groups reduced alcohol  
37 consumption outcomes three months later compared with those in the SC group. Such  
38 decrease agrees with that found in similar studies conducted in high-income countries (Chang  
39 et al., 2005; Handmaker et al., 1999; Marais et al., 2011; O'Connor & Whaley, 2007; Sheehan  
40 et al., 2014), and in a single study examining BI in Latin American pregnant women (Aliane,  
41 2013).  
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50 On the one hand, this finding shows that receiving either a BI or BA is more beneficial  
51 than receiving the regular care provided by the prenatal health care centers. On the other hand,  
52 it is interesting to note that women who were in BI and BA group were enrolled in the study  
53 when they were about 3-4 months of pregnancy and women in SC group when they were  
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4 about 5-6 months of pregnancy. Therefore, results suggest that it is better to receive screening  
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6 and advice about alcohol earlier in pregnancy than at a later stage.  
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9 According to GEE analysis, there were no statistical differences between BI and BA.  
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11 However, the clinical significance analysis shows a favorable risk reduction of quantity and  
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13 frequency of consumption among BI participants. Additionally, the number of women  
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15 necessary to treat to have a beneficial outcome is low. However, the effect demonstrated in  
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17 favor of BI compared to BA is small.  
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21 The lack of differences between BI and BA could be explained by two factors. First,  
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23 there is evidence in the alcohol field that shows assessment reactivity, which results in a  
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25 reduction of harmful alcohol outcomes when participants are asked about their alcohol habits  
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27 (Meier et al., 2017). Previous studies among pregnant women have demonstrated reductions  
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29 in alcohol consumption among both BI and control groups (de Paula Gebara et al., 2013;  
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31 Nilsen, 2009). Also, screening measures such as the AUDIT have been considered to act as an  
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33 intervention itself (Nilsen et al., 2008). Secondly, in our study participants who were in the  
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35 BA condition received a clear abstinence message in the form of a brochure personally  
36  
37 handed out, in a context where such information is not easily available to them. Previous  
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39 studies have shown that in Argentina only 10% of women in prenatal care received clear  
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41 advice on alcohol abstinence (López, 2013). It is possible that in our context, pregnant women  
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43 drink alcohol due to a lack of information about the risks involved. That is why for most  
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45 women screening and a clear abstinence message could be enough to motivate behavioral  
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47 change and discourage consumption. However, futures studies should investigate which  
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49 pregnant women can benefit from BA and under which circumstances it might be necessary to  
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51 perform a BI.  
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57 **The second part of our study included** an objective outcome measure, stressed by  
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59 experts as a necessity in resolving the conflicting evidence from many BI studies (Glass et al.,  
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4 2017). We have thus assessed newborns' health indicators from mothers in BI and BA  
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6 conditions, alongside those mothers who did not receive screening or any intervention (NSC).  
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8 Birth weight and gestational age were significantly higher among those newborns whose  
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10 mothers received either the BI or BA compared to the NSC. Although there are only a few  
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12 studies in pregnant women that used objective outcome measures together with self-reported  
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14 consumption, their results are similar to ours. Babies whose mothers received an intervention  
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16 similar to BI have better birth weight (Armstrong et al., 2009; O'Connor & Whaley, 2007;  
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18 Tzilos et al., 2011) and gestational age (Armstrong et al., 2009) than babies from screening  
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20 only groups.  
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25 Our results must be considered in light of some limitations. First, only 56% of the  
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27 participants could be reached for follow-up **in the first part of our study**, a higher rate than  
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29 most studies (Joseph & Basu, 2017). **Retention is a recognized problem of RCTs and**  
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31 **strategies regarding this have been studied (Gillies et al., 2021). Our study did not include an**  
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33 **economic compensation for participation, which may increase retention. Also, follow-up**  
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35 **contacts were made only by phone. Participants may not have answered since they not**  
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37 **recognized the phone number, thus including online forms sent by e-mail or text messaging**  
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39 **could improve follow-up rates.** Second, due to ethical reasons, it was not possible to randomly  
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41 assign the four conditions which we include here (BI, BA, SC, and NSC), and which might  
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43 have introduced a seasonal bias. However, if results were thus affected, it was probably in the  
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45 direction of underestimating the interventions' effect, since participants in the screening only  
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47 control group were evaluated during the winter months while those in BA and BI groups were  
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49 assessed during spring, when consumption may increase due to seasonal factors. Third, we  
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51 delivered BI or BA among women up to 26 weeks pregnant. This may be different from most  
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53 studies among high-income countries which usually use a shorter range of gestation. We  
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4 considered this necessary because in Argentina most women acknowledge their pregnancy  
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6 late.  
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9       Regarding measurements, we considered alcohol consumption before and after  
10 pregnancy recognition, instead of pregnancy conception. Although pregnancy recognition  
11 could vary among women, data about pregnancy conception was not available. Moreover, we  
12 evaluated as efficacy whether women who did not consume alcohol after recognizing the  
13 pregnancy maintained their abstinence. It is necessary to take this into account because it is  
14 possible that some of these women would had maintained abstinence without any  
15 intervention. Also, possible recall bias might have occurred, as there was a longer time lapse  
16 in assessment for SC participants compared to those in the BI and BA groups. Furthermore,  
17 results about newborns health indicators should be interpreted with care considering that these  
18 data were only obtained on 30% of newborns delivered by women in the BI and BA groups.  
19 Although some biases may be introduced from low follow-up rates and resulting sample sizes,  
20 the use of an objective outcome is still a novelty and other similar studies should be done to  
21 confirm the effects of BI and BA on newborn health indicators.  
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39       Finally, although our sample was representative of all women receiving antenatal care  
40 in the public health system in an Argentinean city, results should not be extended to other  
41 populations without further considerations. Future studies should assess efficacy of BI among  
42 pregnant women in private care, where a higher educational level and perhaps more  
43 information about the risk of prenatal alcohol exposure may produce different findings.  
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50       Despite limitations our results point to the efficacy of screening and delivering either  
51 BA with a clear abstinence message or a BI among pregnant Argentinean women.  
52 Importantly, while many studies have evaluated the efficacy of BI early in pregnancy,  
53 findings from this study suggest that BI may be effective as late as the third trimester of  
54 pregnancy, during which time the fetus is gaining weight.  
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4                   Considering the results of this study, implementation of BI or BA in routine antenatal  
5 care is an opportunity that is missed. For example, many women detected with possible AUD  
6 by prenatal alcohol screening may not otherwise be detected by the health care system. BI has  
7 the advantage of identifying and addressing risky consumption in a circumscribed amount of  
8 time, and its characteristics encompass a referral to treatment, reducing stigmatization.  
9 Despite the advantages of BI, BA is an even shorter tool than BI and also demonstrated  
10 effectiveness. Lack of time and resources in prenatal care should not be considered a barrier  
11 to implementing an intervention. Also, it is necessary to develop guidelines for addressing  
12 alcohol consumption during pregnancy, providing the requisite support for physicians and  
13 other health care professionals in conducting brief interventions in prenatal settings.  
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27                   Our results contribute to leveling the evidence disparity between the northern and  
28 southern hemisphere and suggest that providing BA or BI could lead to healthier babies.  
29 Since epigenetic studies have shown that negative consequences of alcohol exposure during  
30 pregnancy could be transmitted through three generations (Mead & Sarkar, 2014), these kind  
31 of interventions would have positive effects not only for the pregnant woman and her  
32 newborn but also for future generations.  
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43 *The authors report no conflict of interest*

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Table 1

*Baseline sociodemographic characteristics of pregnant women by condition, N=640*

	Brief intervention N=252	Brief advice N=234	Screening control group N=154	$X^2$	$p$
<i>Marital status %</i>				9.73	.285
Married/Civil union	77.4	81.2	80.5		
Separated/Divorced	1.6	1.7	3.2		
Single	21	17.1	16.2		
<i>Educational Level %</i>				13.21	.510
Primary	19.1	17.6	15.7		
High School	70.2	69.7	67.3		
High Education	10.8	12.8	17		
<i>Occupation %</i>				22.1	.077
Employed	10.7	11.7	8.2		
Underemployed	10.7	19.1	10.9		
Unemployed	26.3	18.2	23.8		
Housekeeper	40.7	41.3	46.9		
Student	9.9	9.1	9.5		
Other	1.6	0.4	0.7		
<i>Age M (SD)</i>	24.25(6.03)	24.84(6.21)	25.12(6.13)	2.68	.262
<i>Gestational week M (SD)<sup>a</sup></i>	15.51(6.66)	15.21(6.20)	30.55(2.8)	.315	.575
<i>Number of children M (SD)</i>	.96(1.27)	1.11(1.85)	1.22(1.31)	6.53	.038
<i>Socioeconomic Status M (SD)<sup>b</sup></i>	17(2.54)	17.26(2.15)	17.32(2.36)	2.01	.366

Note: a Comparison between Brief intervention and Brief advice

<sup>b</sup> According to the GRAFFAR scale (Castellano & Mendez, 1994).

Table 2.

*Descriptive information on alcohol consumption outcomes by group, pregnant women, Argentina*

Variables	Brief intervention			Brief advice			Screening control group	
	BPR	APR	Follow-Up	BPR	APR	Follow-Up	BPR	Late pregnancy evaluation
<i>Quantity M(DS)</i>	2.69(3.03)	.27(.58)	.13(.64)	2.82(2.74)	.28(.6)	.15(.42)	2.16(1.42)	.44(.7)
<i>Frequency %</i>								
Never	--	79	92	--	79	88	--	67
Once a month	51	17	6	49	18	9	56	29
2-4 times a month	43	4	2	45	3	3	40	4
2-3 times a week	2	--	--	1	--	--	3	--
4 or more times a week	4	--	--	5	--	--	1	--
<i>Binge drinking %</i>								
Never	62	100	99	53	100	100	66	99
Less than once a month	21	--	1	23	--	--	20	1
Monthly	10	--	1	13	--	--	9	--
Weekly	6	--	--	9	--	--	5	--
Daily	1	--	--	2	--	--	--	--
<i>Alcohol-related problems M(DS)</i>	1.04(2.77)	.11(.73)	0(0)	.88(2.29)	.03(.39)	0(0)	.44(1.62)	0(0)

Note: BPR= Before pregnancy recognition, APR= After pregnancy recognition.

Table 3

*GEE models for alcohol consumption outcomes, pregnant women, Argentina*

Predictors	Quantity			Frequency			Binge drinking		
	Wald $\chi^2$	B(SE)	CI 95%	Wald $\chi^2$	B(SE)	CI 95%	Wald $\chi^2$	B(SE)	CI 95%
<i>Model 1. BI vs BA</i>									
Intervention (ref: BA)	.455	.17(.26)	-.33 to .67	.003	.02(.28)	-.53 to .56	2.07	-.92(.64)	-.2.18 to .33
Time	157.5**	-1.65(.13)	-1.91 to -1.39	124.37**	-1.67(.15)	-1.38 to -1.96	49.54**	-3.36(.48)	-4.29 to -2.42
Intervention*Time	.60	-.16(.20)	-.55 to .24	.001	.01(.19)	-.36 to .37	.71	-.5(.59)	-.66 to 1.65
Number of children	.219	-.02(.04)	-.09 to .05	.841	.04(.04)	-.04 to .12	9.14**	-.25(.08)	-.41 to -.09
<i>Model 2. BI, BA vs SC</i>									
Intervention BI (ref: SC)	63.37**	1.93(.24)	1.45 to 2.4	101.07**	3.93(.39)	3.16 to 4.7	15.6**	1.85(.47)	.93 to 2.77
Intervention BA (ref: SC)	86.25**	1.76(.19)	1.39 to 2.13	121.21**	1.76(.19)	3.09 to 4.43	20.74**	2.76(.61)	1.57 to 3.95
Time	79.68**	-.66(.07)	-.81 to -.52	110.47**	-.87(.08)	-1.03 to -.71	37.7**	-1.30(.21)	-1.72 to -.89
Intervention BI*Time	16.56**	-.88(.21)	-1.31 to -.46	35.19**	-1.57(.26)	-1.31 to -.46	2.41	-.65(.42)	-1.47 to .17
Intervention BA*Time	22.29**	-.72(.15)	-1.01 to -.42	39.83**	-1.3(.21)	-1.01 to -.42	3.91*	-1.12(.57)	-2.24 to -.01
Number of children	4.49*	-.07(.03)	-.14 to -.01	6.97**	-.15(.06)	-.26 to -.04	12.14**	-.26(.07)	-.40 to -.11

Note: BI= Brief intervention, BA= Brief advice, SC=Screening control group, CI= Confidence interval.

\*\*  $p < .01$

\*  $p < .05$

Table 4.

*Clinical significance analyses for alcohol-related outcomes among pregnant women receiving BI vs BA, Argentina (N=640)*

	Quantity	Frequency	Binge drinking	Alcohol-related problems
RR (CI 95%)	0 .91 (0 .76 to 1 .09)	0 .9 (0 .75 to 1 .08)	0 .98 (0 .81-1 .19)	0 .96 (0 .79-1 .17)
ARR (CI 95%)	4 .65% (-3 .98% to 13 .37%)	5 .09% (-3.53% to 13 .82%)	0 .97% (-7.68% a 9 .63%)	1 .74% (-6.9% a 10 .4%)
NNT (CI 95%)	22 (7 to -25)	20 (7 to -28)	103 (10 to -13)	58 (10 to -14)

*Note.* CI= confidence interval, BI= Brief intervention, BA= Brief advice.

Table 5.  
 Comparison of newborns' health indicators whose mothers received BI, BA or NSC, Argentina  
 (n=295)

Groups	Variables	W	Cliff's delta
BI vs BA	Weight at birth	2606	--
	Gestational age at birth	2510	--
BI vs NSC	Weight at birth	6917*	.20
	Gestational age at birth	7160**	.24
BA vs NSC	Weight at birth	6072*	.19
	Gestational age at birth	6488.5**	.27

Note. BI = brief intervention; BA= brief advice; NSC= non screening control; \* $p < .05$  \*\* $p < .01$

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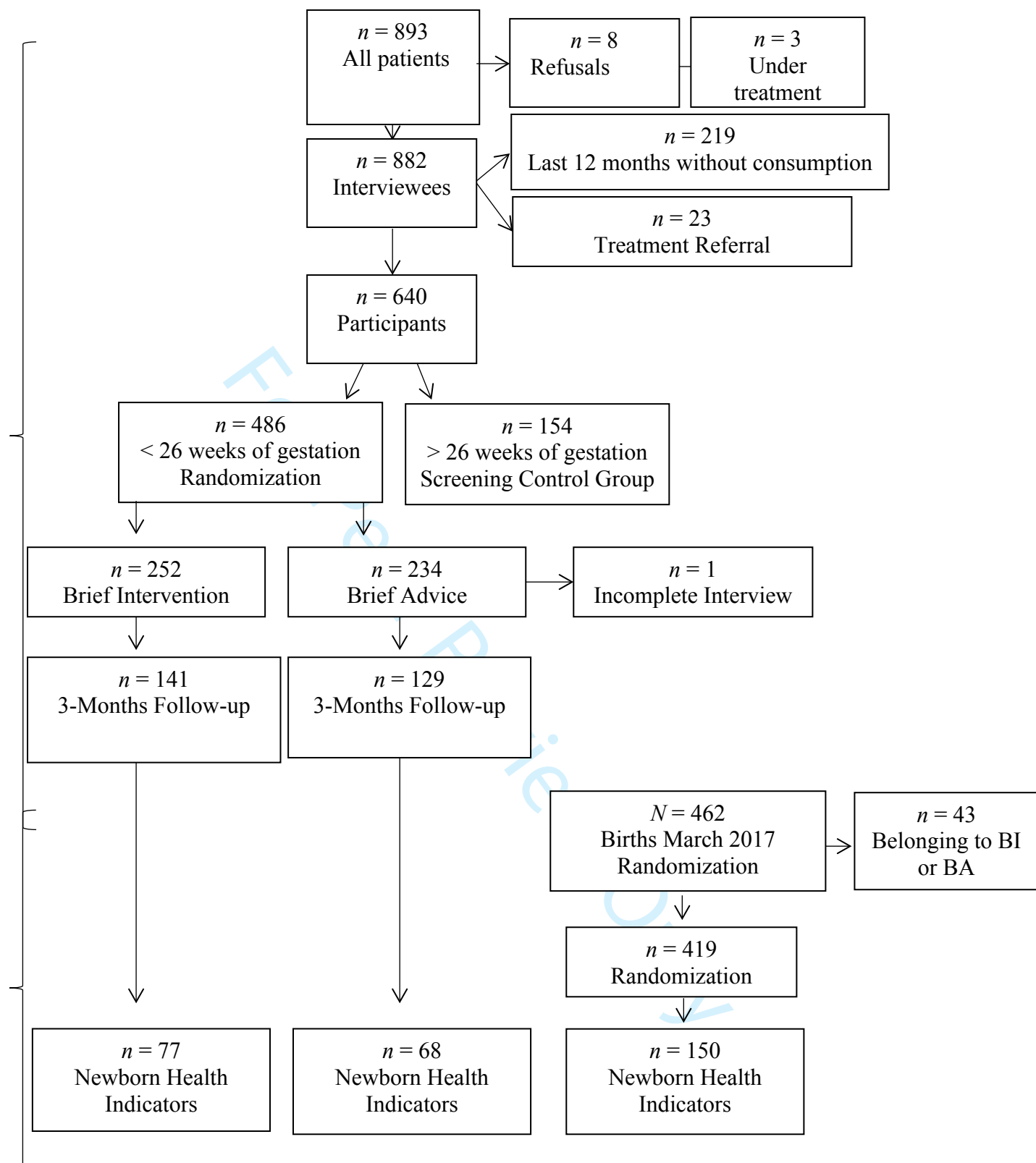


Figure 1. Participants flow chart