A realist evaluation of an antenatal programme to change drinking behaviour of pregnant women

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A B S T R A C T
Objective: to use realist evaluation to describe and explain how and in what circumstances screening and alcohol brief interventions work in routine antenatal care.

Design: a realist evaluation incorporating systematic reviews and qualitative data.

Setting: NHS Lothian, which is one of the 14 Scottish health boards.

Participants: participants were recruited from two maternity units. In phase one, interviews were conducted with four participants responsible for policy implementation. These data were supported by two systematic reviews. In phase two, 17 pregnant women and 15 midwives participated in interviews, with a further six midwifery team leaders involved in a focus group.

Findings: training and resources provided to midwives as part of the programme acted as facilitating mechanisms that improved their skills and confidence to screen and deliver alcohol brief interventions. The programme elicited positive change in attitudes to drinking in pregnancy and possibly stimulated drinking behaviour change amongst pregnant women. However, the small numbers of pregnant women being identified for alcohol brief interventions meant delivery was infrequent and resulted in the programme not working as anticipated. The findings also revealed contextual issues around midwife–pregnant woman relationship and the challenges of negotiating the timing of screening and alcohol brief interventions delivery.

Conclusions: Drinking in pregnancy is an emotive issue, therefore delivering alcohol brief interventions at the first antenatal appointment when they are more likely to achieve the most benefits poses challenges. When training midwives to screen and deliver alcohol brief interventions, special attention is needed to improve person-centred communication skills to overcome barriers associated with discussing sensitive prenatal alcohol use and enhance early identification and delivery of alcohol brief interventions at the first antenatal appointment.

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Introduction

Drinking alcohol during pregnancy can be a threat to the health of an unborn child, with extreme cases manifesting as fetal alcohol syndrome (Jones et al., 1973; Stratton et al., 1996; Damgaard et al., 2007). Screening and alcohol brief interventions (ABIs) – often described as a package – can reduce alcohol consumption and therefore contribute to the prevention of alcohol-related risk to the unborn child. Alcohol brief interventions are opportunistic in nature and are offered to individuals who are not directly seeking help for alcohol problem but have been identified by alcohol screening as drinking beyond recommended levels (Heather, 2012). They are described as behaviour change interventions that can range from a single 10–15 minutes session to several sessions (Heather, 2004; Vasilaki et al., 2006; Heather, 2012). The specific components of ABIs are debatable (Moyer et al., 2002). However, they usually include assessment, personalised feedback about drinking behaviour, goal setting, behaviour modification strategy and minimal follow-up reinforcement visits or ongoing support (Heather, 2004; Chang et al., 2005).

It has been estimated that about 25% of women in Scotland consume alcohol whilst pregnant (Ford, 2008). In 2008, the Scottish...
Government, as part of its wider plans to reduce alcohol-related harm in Scotland, implemented screening and ABIs in a number of health-care settings including antenatal care in an effort to protect the health and safety of the unborn child and improve subsequent health and developmental outcomes (McAuley, 2009; Scottish Government, 2011). Midwives who provide antenatal care received half a day face-to-face screening and ABI skills training as part of the initiative. The guidance for midwives is as follows. At the first antenatal appointment, they are asked to enquire about pregnant women’s drinking behaviour. For pregnant women who indicate that they have consumed alcohol, further questions are then asked to ascertain their level and pattern of drinking (NHS Health Scotland, 2015). Women who choose to consume alcohol but at a level within the national guidance of not more than 2 units, once or twice a week are reminded of the current national guidance on drinking in pregnancy and advised that abstinence is the safest approach. However, for women who are currently drinking more than the national guidance, but who did not meet the criteria of alcohol dependence, an ABI should be delivered using the FRAMES approach (Feedback of risk, Responsibility of individual, Advice to change dependence, an ABI should be delivered using the FRAMES approach (Bien et al., 1993; NHS Health Scotland, 2015).

The effectiveness of ABIs may vary, according to setting and the population group. It is now established that, among primary care patients, screening and ABIs can reduce hazardous and harmful alcohol consumption (Bertholet et al., 2005; Kaner et al., 2009). However, evidence of their effectiveness in other settings for example, emergency departments and antenatal care seems inconclusive (Havard et al., 2008; Gilinsky et al., 2011). Public health interventions are often influenced by their context because populations differ by place, characteristics and time (Rychetnik et al., 2002; Bhopal, 2009). For example, the underlying characteristics, such as gender and age of patients attending primary care are different from women attending for antenatal care, and the reasons for attending these health-care services are also different. Therefore, screening and ABIs might work differently in various population groups and settings. In antenatal care setting, it is unclear how they work. Over the years, the focus of screening and ABI research has been on investigating their efficacy and effectiveness, but there is a need to understand how they work and how their effectiveness can be improved (Heather, 2010). Therefore the aim of this realist evaluation of the programme was to explain how and in what circumstances screening and ABIs work in routine antenatal care.

**Methods**

**Theoretical approach**

This study employed realist evaluation principles (Pawson and Tilley, 1997). Realist evaluation is a theory-driven approach to evaluation of social programmes, developed in response to recent interest in understanding how interventions or social programmes work rather than providing success or failure assessment of their effectiveness (Pawson and Tilley, 1997; Bonell, 2002; Mcevoy and Richards, 2003; Pawson, 2006). Pawson and Tilley (1997) argued that programmes are often introduced within complex social systems, which are in constant transformation, therefore evaluation needs to take account of the context within which they are implemented. As such, realist evaluation is useful in terms of understanding why an intervention produces dissimilar outcomes when implemented in different settings. It describes what mechanisms (how people interpret and act upon ideas and opportunities presented by the programme) cause which outcome (intended or unintended consequences) and in which context (social and cultural conditions external to the interventions) (Pawson and Tilley, 1997). This is often denoted as context (C) and mechanism (M) and Outcome (O) configurations. Wilson and Mccormack (2006) explained that mechanisms of causation always occur within a particular context and it is important to understand their relationship and how they influence outcomes. In order for realist evaluation to contribute to the improvement of programmes and offer greater external validity to their findings, it places emphasis upon what makes programmes work, for whom, how and under what circumstances (Pawson and Tilley, 1997; Pawson 2002; Wand et al., 2010).

Realist evaluation seeks to build initial programme theories, test and refine them. The initial sets of programme theories are propositions which span context, mechanism and outcome and drive the remaining aspects of the evaluation (Pawson and Tilley, 1997; Rycroft-Malone et al., 2010; Wand et al., 2011; Cheyne et al., 2013). Driven by these principles, this study proceeded in three key phases as depicted in Table 1.

**Phase 1: Identifying programme theory**

**Data collection.** Programme theory may be derived deductively, inductively or formulated from stakeholders mental models (Funnell and Rogers, 2011). Deductive development involves developing the programme theory from a review of the research literature on how the programme is understood or expected to work. Whereas, inductive development encompasses inferring the programme theory from how the programme operates in practice based on observations or interviews with staff. Formulation of programme theory from stakeholders’ mental models involves drawing out the concepts of how they understood or anticipates the programme to work. Funnell and Rogers (2011) suggest that meaningful programme theory should be developed from an appropriate mix of these three elements. We formulated programme theories by undertaking semi-structured interviews with four policy stakeholders responsible for developing and overseeing the implementation of the screening and ABIs. The

**Table 1**

<table>
<thead>
<tr>
<th>Phase</th>
<th>Source of data and activity</th>
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| Phase 1 – Identification of programme theory or hypotheses about Context-Mechanism-Outcome (CMO) configurations | - Two systematic reviews  
- Interviews with four programme implementers/ policy stakeholders |
| Phase 2 – Testing the programme theory | - Interviews with a focus group with 21 midwives  
- Interviews with 17 pregnant women |
| Phase 3 – Refining the programme theory | - Analyses and interpretation  
- Refined Context-Mechanism-Outcome (CMO) configurations |

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interviews explored stakeholders’ accounts of the rationale, expectations and key aspects of the implementation of the programme. We also inquired about anticipated barriers and facilitators (topic guide available on request).

The interviews were complemented by conducting two systematic reviews. The first examined observational studies that considered the effects of alcohol use on the unborn child and the second examined the current evidence base for screening and ABIs in various health-care settings (Doi, 2012). The interviews and systematic reviews together provided data that were used to formulate the programme theories.

**Analysis of qualitative data.** The qualitative data were analysed thematically (Fereday and Muir-Cochrane, 2006). Both inductive approach (codes emerging from the data) (Boyatzis, 1998) and deductive approaches (codes developed from the research question) were used (Crabtree and Miller, 1999). The main stages of the data analysis were: development of a code framework; testing reliability of codes; identification of initial themes emerging from the data; utilisation of code manual to apply codes to entire transcripts whiles noting emerging codes; connection of codes into themes and corroboration of themes through interpretation of analysis (Fereday and Muir-Cochrane, 2006). A deductive a priori code template was developed using the core concepts of realist evaluation - context, mechanism and outcome - as the main imaging tool (Marchal et al., 2012). These three broad concepts were further defined by their constituent parts. For example, context included codes such as institutional conditions (routines), cultural norms and values and wider national policies. Using NVivo (QSR International, 2011), two members of the research team independently proceeded with data analysis by selecting the appropriate segments of text and coding them appropriately. This produced several free codes. New codes were added when new ideas emerged from the data until a final code manual was produced. Further, similar codes were grouped together to form overarching themes. Overall, five themes were identified: (1) policy drivers and training; (2) clinical settings; (3) attitudes of women and midwives; (4) perceived benefits of ABIs; and (5) barriers and challenges.

Another member of the research team then verified transcripts and ensured that they appropriately reflected their themes. The data was then synthesised to identify patterns of meaning, similarities and differences. The analysis then advanced to the interpretative phase, where the findings of the systematic reviews complemented the generation of programme theories about what mechanism are operating, in what context, and to produce what outcomes.

**Phase 2: Testing programme theory**

**Data collection.** The programme theories were tested through semi-structured interviews and a focus group with 21 midwives involved with screening and delivering ABIs and 17 pregnant women who received the screening and/or ABIs. Participants were identified by purposive sampling. Midwives and pregnant women that participated were recruited from one (of a total of 14) Scottish health board, NHS Lothian. This NHS board has two consultant-led maternity units and around 130 community midwives providing community-based antenatal care. Midwives received the study information pack, containing an invitation to participate in the study through their team leaders. Whereas pregnant women received the study information sheet through their midwives. A member of the research team contacted interested participants individually to arrange an interview or focus groups. Signed consent forms from participants were obtained prior to data collection. All the interviews and the focus group were audio-recorded and transcribed verbatim by the first author.

Semi-structured interviews and the focus group topic guides (available on request) were developed to reflect the findings of phase one and to examine how the programme unfolded in practice. Briefly, midwives were asked to discuss their experiences of screening and delivering of ABIs, including barriers and facilitators and the influence of the programme on the midwife-pregnant woman relationship. Pregnant women discussed their experiences of how they reacted to the screening and/or brief interventions.

**Analysis of qualitative data.** The qualitative data were analysed as described in phase one. Pregnant women and midwives data were analysed in parallel. However, the midwives focus group and individual interview data were analysed together as only one focus group was conducted and it followed a similar structure as the interviews. Interpretations of the analysis at this stage focused on testing the programme theories formulated in phase 1.

**Phase 3: Refining programme theory**

The initial programme theories, developed in stage one, were compared and contrasted with midwives’ and pregnant women’s findings from stage two and then synthesised to offer explanations to how the programme unfolded or did not unfold in antenatal care setting.

**Ethics**

The study received ethics approval from the West of Scotland Research Ethics Committee 2. The study complied with research governance procedures in NHS Lothian.

**Findings**

**Phase 1: Developing the programme theory**

Hypothesising the programme theory began with a review of the evidence linking alcohol consumption with adverse fetal outcome. It was evident that the fetus is particularly at risk during the first trimester. Also, while there was consistent evidence of risk regarding heavy-sustained prenatal drinking, evidence pertaining to low to moderate levels varied. We hypothesised that these inconsistencies might influence pregnant women’s attitudes to drinking and impact on midwives’ attitudes and practices of screening and ABIs. A second systematic review of reviews also examined the evidence of effectiveness of screening and ABIs across different health-care settings – primary care, emergency department, general hospital ward and antenatal care. It appeared that screening and ABIs had only a modest evidence base in antenatal care. We hypothesised that in order for the programme to achieve optimum effectiveness there should be adequate training and support systems available to midwives.

The four policy stakeholders described the drivers behind the implementation of the ABI programme and their anticipation of how it was expected to work. They also outlined challenges and other underlying issues around the implementation of the programme. The main programme driver was a perceived concern about an upward trend of alcohol-exposed pregnancies and the desire to protect the health and safety of the unborn child. They also highlighted the ‘captive’ audience and the teachable moment that pregnancy presents, as an opportunity for the programme to work. They felt that the programme might, perhaps elicit long-term drinking behaviour change benefits for women. However, stakeholders recognised that midwives current heavy workload might be a challenge in terms of incorporating the programme into routine practice. Stakeholders felt that the programme was likely to succeed because it was considerably supported by the
Scottish Government. There was also anticipation that the provision of ABI delivery skills training would promote midwives’ confidence and improve quality of screening and delivery.

The programme components and anticipated CMOs

On the basis of the reviews and interviews with stakeholders, three main theory areas were identified. These were uncertainties of fetal outcomes, antenatal appointment and training and support. These theory areas were used to construct the initial CMO configurations (see Table 2).

Phase 2: Testing the programme theories

All midwives who participated in the study were trained to screen and deliver ABIs as part of the programme. They all indicated that they had identified pregnant women who drank alcohol. Midwives comprised of consultant midwives, team leaders and community midwives. Their years of service ranged between 3 and 33. Around 70% stated that they had screened and delivered ABIs. Seventeen pregnant women aged 21–43 years took part in the study. They all had undergone screening for alcohol consumption in pregnancy but none explicitly indicated that they had received ABIs. The findings of the midwives and the pregnant women qualitative interviews have been reported elsewhere (Doi, 2012; Doi et al., 2014) and have been summarised in Appendices A and B.

Phase 3: Refined programme theories

Theory area one: uncertainties of risk (Table 3)

It appeared that the programme had a positive influence on the knowledge of midwives and pregnant women regarding the risk of drinking during pregnancy. Particularly midwives acknowledged that their understanding of risk had improved after the training programme. Midwives created awareness about alcohol use in pregnancy through screening and imparted knowledge to women by informing them about the range of conditions associated with antenatal alcohol consumption. This acted as facilitating mechanism as some women appeared to comply with their midwives’ advice. Both midwives and pregnant women showed positive attitudes towards abstaining or reducing alcohol consumption during pregnancy.

In the context that drinking below moderate levels poses minimal risk to the fetus, the ability of women to estimate low or moderate alcohol units might be critical. The subtle programme mechanism appeared to be successful by presenting midwives with opportunity to educate women about estimating units of alcohol in alcoholic beverages. Therefore, the mechanism worked by offering midwives opportunity to offer women who still wished to drink the necessary knowledge to make informed decisions. For women who decided to abstain from alcohol, it reinforced the benefits of abstinence.

Theory area two: antenatal appointment (Table 4)

Motivational interviewing, the technique often used for delivering ABIs thrives more on properly developed relationships (Rollnick and Allison, 2004; Woolard et al., 2011). Pregnant women revealed that trust was important for them to freely disclose sensitive information regarding antenatal alcohol consumption. Midwives indicated that carrying out ABI activities at the first appointment, especially at that early stage when strong relationships with women had not been established was challenging. The constraining mechanism that was identified was that pregnant women who did not establish an adequate rapport with midwives...
Table 3  
Refined CMOs for component 1: uncertainties of risk.

<table>
<thead>
<tr>
<th>Context</th>
<th>Mechanism</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncertainties of risk to the fetus regarding the effects of lower levels of alcohol consumption</td>
<td>Midwives 1. Greater understanding of risk after undergoing ABI skills training so provided relevant alcohol advice to women 2. Women empowered to estimate alcohol units</td>
<td>Midwives 1. Improved understanding of risk promoted positive change in attitudes 2. Improved capacity of alcohol assessment helped women to make informed alcohol consumption decisions</td>
</tr>
<tr>
<td></td>
<td>Pregnant women Opportunities for women to discuss uncertainties of risk with midwives</td>
<td>Pregnant women Increased awareness of the risks of drinking in pregnancy positively influenced attitudes to antenatal alcohol consumption</td>
</tr>
</tbody>
</table>

Table 4  
Refined CMOs for component 2: antenatal appointment.

<table>
<thead>
<tr>
<th>Context</th>
<th>Mechanism</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 + 2. Midwife–pregnant woman relationship at first appointment 3/4. Period of screening and delivery of ABIs more important as effects of drinking in first trimester is more profound</td>
<td>Midwives 1. Use of ‘motivational interviewing style’ or good person-centred communication skills necessary to overcome unfamiliarity 2. Screening and ABIs delivered in the midst of other competing issues</td>
<td>Midwives 1. Improved identification of risky drinking 2. Missed opportunities and declined priority</td>
</tr>
<tr>
<td></td>
<td>Pregnant women 1. Uneasiness about alcohol consumption disclosure at first appointment 2. Credibility of midwives adds value to their advice and facilitated change 3. Enquiry about alcohol consumption and exploration of the number, nature and size of drinks consumed prompted behaviour change 4. Early identification and intervention more critical</td>
<td>Pregnant women 1. Provision of socially desirable response about drinking behaviour 2. Increased adherence to midwives’ advice 3. Women reduced or abstained from alcohol after alcohol assessment 4. More risk to the fetus reduced and subsequent maternal drinking behaviour altered</td>
</tr>
</tbody>
</table>

Table 5  
Refined CMOs for component 3: training and support.

<table>
<thead>
<tr>
<th>Context</th>
<th>Mechanism</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Midwives 1. Training and support provided to midwives 2. Few women consuming alcohol meant less ABIs delivered</td>
<td>Midwives 1a. Training equipped midwives with adequate knowledge and understanding of the risks of drinking in pregnancy 1b. Adequate support and materials provided, which aided screening and ABI delivery 1c. Raised priority and eliminated initial resistance 2. ABI delivery skills rarely used</td>
<td>Midwives 1a. Added value to practice and renewed urgency among midwives to make a difference 1b. Greater support from stakeholders 1c. Improved engagement from midwives 2. Reduced priority for ABI activities</td>
</tr>
</tbody>
</table>

at the first antenatal appointment appeared to refrain from disclosing their true drinking levels.

Although most of the women had stopped or reduced alcohol intake once pregnancy was confirmed, there was some evidence that women adhered to the alcohol consumption advice provided by their midwives. This was considered as a facilitating mechanism because most women reported that they had reduced or abstained from alcohol after their first appointment (usually about 8–12 weeks). There was also the perception that that merely the act of midwives inquiring about the number, nature and size of drinks consumed prompted women to alter their drinking behaviour.

There was a consensus among midwives that the programme was competing with other equally, if not more important issues at the first antenatal appointment. For instance, the programme received a low priority in midwives workload for women who had significant other problems aside from drinking (e.g. domestic abuse issues). This was considered as a constraining mechanism because in the context of competing priorities, there were indications that some midwives missed opportunities to deliver ABIs due to time constraints. Instead, they deemed it more appropriate to refer pregnant women who drank at risky levels, and qualified for ABI to other health-care practitioners.

Most of the women in this study drank some alcohol early in the first trimester before pregnancy was confirmed. Women who had consumed large quantities of alcohol prior to their first antenatal appointment, posed a challenge for the programme. Because drinking in the first semester is associated with increased risk to the fetus (Whitty and Sokol, 1996; Sayal et al., 2007),
Nevertheless, the programme could be beneficial for altering drinking behaviour for the remainder of the pregnancy and possibly for future pregnancies.

Theory area three: training and support (Table 5)

The screening and ABI skills training acted as a facilitating mechanism as it equipped midwives with adequate knowledge and understanding of the risks of drinking in pregnancy. They perceived that their skills and confidence of screening and delivering ABIs had improved. This enhanced skills of midwives probably had direct benefit for pregnant women in their care.

Furthermore, the screening and ABI skills training was essential in raising the priority of the programme. There was a renewed urgency among midwives about the need to intervene as they recognised the Scottish Government’s commitment to preventing alcohol-exposed pregnancies. It also facilitated midwives acceptance of screening and ABIs as part of their role. In the context that training and support were essential for screening and ABI delivery, the facilitating mechanisms worked because training and support negated considerable numbers of practitioners’ barriers detailed around lack of adequate confidence and skills that have been reported in other studies (Lock et al., 2002; Tsai et al., 2010).

Most women naturally reduce alcohol consumption when they know they are pregnant. Both midwives and women affirmed this. As described above, training promoted midwives confidence and it was perceived that lack of regular opportunity to deliver ABIs negatively affected midwives ABI delivery skills. Under these circumstances, the screening and ABIs programme worked for midwives who regularly delivered them to women. The low ABI delivery numbers was considered as a constraining factor because it influenced the perception of midwives and prompted some to conclude though tentatively, that alcohol consumption during pregnancy was after all not so pertinent. This resulted in a perceived decrease in priority of screening and ABI activities.

Discussion

The opportunity pregnancy brings encouraged the Scottish Government to implement screening and ABIs in antenatal care setting despite their limited evidence base. Although in the past few decades, efforts have been made to build the evidence base of screening and ABIs in primary care setting, primarily because it is the setting where heavy drinking and alcohol problems are most likely to be encountered (McCambridge, 2013). However, because brief interventions are ‘motivational’ in nature, delivering them at antenatal setting where women are more concerned with the health of the unborn child may persuade more women to stop drinking for the remainder of their pregnancy although it is unclear whether this benefit will continue after the pregnancy. In this study, we found that the screening and ABI programme improved midwives and pregnant women understanding of the risk involve with prenatal alcohol consumption. The ABI skills training was perceived as successful in terms of raising the priority of the programme and equipping midwives with the necessary skills and confidence to screen and deliver ABIs. However, delivering ABIs at the first antenatal visit where the unborn baby had already been exposed to some alcohol and most women had stopped drinking alcohol prompted some midwives to doubt the purpose and the value of the programme in antenatal care setting.

The context of delivering ABIs at the first antenatal visit where there was inadequate rapport between midwives and women and time constraints issues presented challenges to the programme.

This study, to our knowledge, is the first to use realist evaluation approach to understand how screening and ABIs work in routine antenatal care setting. Although there have been a number of studies that have evaluated screening and ABIs with antenatal care populations, most of them focused on their efficacy (Chang et al., 1999, 2005; O’Connor and Whaley, 2007) rather than the underlying processes and mechanisms. A recent systematic review showed that there was some evidence from a small number of studies that a single session face-to-face ABI resulted in maintaining abstinence from alcohol during pregnancy. However, the review concluded that a more intensive intervention might be required to encourage women who continue to drink during pregnancy to reduce alcohol consumption (Gilinsky et al., 2011). This conclusion is at variance with the findings of this realist evaluation that midwives conferred ABIs low priority in their workloads, especially for women who had other challenges aside from alcohol. There is also evidence that when health professionals are preoccupied with other concerns, opportunity to deliver alcohol interventions to pregnant women are missed (Chang et al., 2008). This calls for a more concerted effort to sustain the priority of the programme in antenatal care and ensures that women who continue to drink in pregnancy receive the necessary support to reduce alcohol consumption when required.

The rationale for this evaluation was not to determine whether the programme ‘worked’ but to explore and explain how it worked (or not) in routine antenatal practice. Realist evaluation was particularly suited for evaluating such a policy initiative as it aims to develop initial programme theories based on policy makers’ concepts of how a programme is expected to work and testing these theories out with practitioners and participants, in order to refine them to improve knowledge of how the screening and ABIs work for whom and in what circumstances (Pawson and Tilley, 1997). Pawson and Tilley (1997) argued that when evaluating social interventions, traditional experimental designs such as RCTs are inappropriate because it is practically impossible to control for all explanatory variables. Experimental designs do not provide us with sufficient details of the events or circumstances that brought about change. They argued that social interventions work only where participants choose to co-operate and this depends on a complex interplay between motivation, circumstances and attitudes. We found that the programme received impetus because it was a Scottish Government’s initiative, adequate training was provided and midwives were willing to add this aspect of care to their practice. Employing realist evaluation helped to unravel some of these nuances and inherent contradictions and dilemmas the midwives faced in establishing relationships with, and managing risky behaviours of pregnant women whilst increasing our understanding of how these factors influenced the programme.

Realist evaluation proposes that identification of programme theories should precede testing and refining those theories (Pawson and Tilley, 1997; Pawson, 2002). In this study, an attempt was made to extensively outline programme theories through conducting reviews and interviewing policy stakeholders. However, during the process of testing the theories with midwives and pregnant women, new concepts were identified which were not initially formulated as programme theories. This often necessitated the need to revisit the initial programme theories in order to accommodate these new concepts. This meant that the process of developing, testing and refining programme theories was not entirely sequential but rather an iterative one. Although, this proved time consuming and complex initially, it nevertheless offered more depth to the analysis.

During the process of developing and refining the CMO configuration, it was often clear that an alternate CMO could be generated. Other studies have also reported similar challenges (Byng et al., 2005; Tolson et al., 2005). However, Rycroft-Malone et al. (2010) indicated that realism, the philosophical base of realist evaluation, makes provision for two or more mechanisms to operate concurrently. Therefore, it was imperative that the final
CMO configurations agreed upon by the research team were informed by the research aims. This study, like most other research projects, has limitations and these should be taken into consideration when interpreting the findings. The study relied extensively on external policy developments regarding the screening and ABI initiative, which were beyond our sphere of influence. For instance, at the start of the study (mid-2009) we understood that the screening and the ABIs would be introduced in antenatal care setting by the end of that year. Yet it was not until the end of the following year before a few Scottish health boards started implementing them. As such, at the time of data collection only few women had been offered the ABIs, therefore obtaining quantitative data to fully explore the behaviour outcome components around pregnant women’s drinking was not possible. With the programme at its early stages, it could be argued that the accounts of the participants provided useful illuminating areas that could further enhance successful embedding of the programme into routine antenatal care. Given the tendency of women to reduce or abstain from alcohol during pregnancy and the challenges of using realist evaluation approach, it was difficult to ascertain whether the intervention actually changed women’s drinking behaviour. Experimental designs, such as RCTs could have eliminated potential explanatory variables and produced specific drinking behaviour outcomes. It may be worth looking more into recent suggestions that conducting a realist evaluation alongside outcome focused evaluation may more likely validate programme configurations agreed upon by the research team.

The face-to-face method of data collection is appropriate for gaining insight into newly implemented projects, but it is open to social desirability and acquiescence bias. It is possible that considering the emotive nature of alcohol consumption in pregnancy, women responded to questions to portray themselves as good mothers. Midwives, with the implicit knowledge that their practice was being examined were likely to respond to questions in ways that suggested that they are adherent to recommendations. Although this threatens the validity of the findings, it is important to note that the findings of realist evaluation can help trigger new studies and provide useful transferable lessons for stakeholders interested in implementing similar programmes elsewhere (Pawson and Tilley, 1997; Wand et al., 2011).

Another issue relates to sample representativeness. The study was undertaken in only one health board in Scotland and as such represented the views of a relatively small number of participants. The findings may therefore not be generalisable to other health boards in Scotland. Albeit, it has provided fundamental insights into issues important to the implementation of screening and delivery of ABIs in routine antenatal care.

## Conclusions

This paper has used realist evaluation to provide an illumination of the fundamental factors influencing the screening and alcohol brief intervention programme in routine antenatal care. It has also showed why the context of antenatal care setting influenced how the programme works. Particularly, drinking in pregnancy is an emotive issue and delivering ABIs at the first antenatal appointment when they are more likely to achieve the most benefits poses challenges. As such, training of midwives to screen and deliver ABIs should focus more on improving skills for example, person-centred communication skills that can help to overcome barriers associated with discussing sensitive antenatal alcohol consumption issues. This can facilitate early identification and ABI delivery at the first antenatal appointment.

## Conflict of interest

The authors declare that there are no conflicts of interest in preparing this manuscript.

## Acknowledgements

We thank all the participants who took part in the study. This work was supported by the University of Stirling.

### Table A1

**Key findings of the midwives qualitative study.**

<table>
<thead>
<tr>
<th>Midwives</th>
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<tbody>
<tr>
<td>Midwives had good understanding of fetal risk of prenatal drinking but a few were sceptical about actual effect on the fetus because they felt the prevalence of the habit did not reflect episodes of harm in infants.</td>
</tr>
<tr>
<td>Increasing workload demands meant that screening and delivery of ABIs were negatively affected at the first antenatal appointment.</td>
</tr>
<tr>
<td>Effective identification and delivery of ABIs were compromised at the first antenatal appointments because the relationship between midwives and women was just being established.</td>
</tr>
<tr>
<td>Midwives perceived that the training and resources improved their confidence.</td>
</tr>
<tr>
<td>Low numbers of ABI deliveries negatively affected midwives skills and confidence.</td>
</tr>
<tr>
<td>Midwives felt screening and ABI was part of their role however, they were demoralised because only few had delivered the intervention.</td>
</tr>
<tr>
<td>Midwives underutilisation of the ABIs limited utility and fidelity.</td>
</tr>
</tbody>
</table>

### Table B1

**Key findings of the qualitative interviews with pregnant women.**

<table>
<thead>
<tr>
<th>Pregnant women</th>
</tr>
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<tbody>
<tr>
<td>The health of the baby was the key reason women said they abstained or reduced alcohol consumption in pregnancy.</td>
</tr>
<tr>
<td>Some women did not consider drinking low levels to be harmful although this perception did not influence their decision whether to drink or not in pregnancy.</td>
</tr>
<tr>
<td>Women who drank in pregnancy without realising that they were pregnant expressed concerns about the health and safety of the fetus, yet some did not discuss such concerns with their midwives.</td>
</tr>
<tr>
<td>ABI might not be particularly beneficial to the current pregnancy in terms of reducing harm to the fetus because a considerable number of women drank in early stages of pregnancy before the first antenatal appointment.</td>
</tr>
<tr>
<td>A good relationship with a midwife was considered necessary to enhance sensitive information disclosure.</td>
</tr>
<tr>
<td>Few women reported that they did not receive ABI and were not followed-up to determine whether they had stopped drinking alcohol even though they indicated at the first appointment that they were drinking.</td>
</tr>
</tbody>
</table>

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Appendix A

See Table A1.

Appendix B

See Table B1.

References


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