

RUNNING HEAD: Stakeholder Perceptions of a RCT

Perceptions of school-based alcohol education by educational and health stakeholders:
'education as usual' compared to a randomised controlled trial.

Abstract

The present study sought the views of stakeholders, including school leaders and statutory stakeholders, on the content and evaluation of a classroom-based alcohol education intervention in a Randomised Controlled Trial in Scotland and Northern Ireland. Purposive sampling was used to ensure that schools from both the Intervention and Control groups were equally represented, and to ensure that similar numbers and grades of stakeholders in both countries were represented. A total of 27 participants (Male = 13 (48%); Female = 14 (52%)) engaged in a semi-structured interview prior to the end of the trial. Results suggest that: schools generally design their own alcohol education programmes; that intervention schools thought highly of the particular intervention tested; and that both groups engaged meaningfully in the research. The threshold for acceptance of the intervention was lower than the successful outcome of the trial. More pragmatic considerations were considered equally important. From the point of view of the statutory stakeholders, funding of an intervention depends on a successful outcome evaluation, but that 'success' may mean a positive impact on at-risk groups, and not necessarily at a universal level. School-based participants also focussed on ease of delivery and user friendliness as key determinants of programme utilisation.

Keywords: Randomised Controlled Trial; Stakeholders; Alcohol; School Context

Introduction

The question of *how* research evidence informs health policy and practice is not a new one (e.g., Cairney, 2016; Champagne & Lemieux-Charles, 2004). In the United Kingdom (UK), the Government Office for Science has produced guidance for both academics and policy makers on this topic, advising how government departments should obtain and use scientific analysis and advice in its policy work (Government Office for Science, 2011; 2013).

Understanding this relationship is important as public funders of academic research are keen that their work has policy impact, researchers want their findings to be integrated into decision-making processes to support implementation and sustainability, and policy makers and practitioners are keen to prioritise those actions with the greatest likelihood of success. However, there is often a misunderstanding of the policy-making process in the general academic community, and an incorrect assumption that decisions are made on the basis of a linear relationship between the production and use of evidence in policy actions (K. A. Oliver, Lorenc, & Innvaer, 2014).

Systematic reviews on evidence-based policy processes, particular at a local level (Innvaer, Vist, Trommald, & Oxman, 2002; K. Oliver, Innvar, Lorenc, Woodman, & Thomas, 2014; Orton, Lloyd-Williams, Taylor-Robinson, O'Flaherty, & Capewell, 2011), provide common findings, namely: the importance of understanding organisational and political barriers to the access, use and interpretation of evidence; the importance of interpersonal relationships in the policy/research interface; the requirement for research findings to be both accessible and clear to the policy maker; and, the disparity in understanding between policy-makers and academics on what is meant by 'evidence'. In particular, reviews by Oliver, Innvæer and their respective colleagues (Innvaer et al., 2002; K. Oliver et al., 2014) highlight

the lack of researcher knowledge about policy maker's attitudes towards and understanding of research evidence.

It has been suggested that local public health policy is often managed and run by 'mid-level managers' with little or no formal training in public health (K. Oliver, de Vocht, Money, & Everett, 2013). One implication of this is that there is a reliance on external sources of information when deciding to commission or implement services and health promotion initiatives as these managers may not possess necessary specialist expertise themselves. However, a wide range of external information sources, individuals, and professionals are consulted, and these comprise a much broader range than is usually perceived by academic researchers. Indeed, academic research alone appears unable to satisfy the requirements of public health policymakers. In one UK study of public health policy-making, Oliver and de Vocht (2015) reported that 'softer' forms of data or information were often valued more by local decision-makers than the findings of studies that would rank highly in traditional scientific evidence hierarchies, and that 'evidence' was interpreted more broadly than classic scientific understandings. Locally sourced evidence included epidemiological data, narratives of historical developments, and qualitative data, as well as knowledge gained through interpersonal interaction, the practice-based knowledge of influential local individuals, and personal knowledge of local organisational systems and structures (Oliver & de Vocht, 2015). In addition to access to and availability of research findings, the quality of pre-existing relationships between academics and policymakers appear to be key determinants in the realisation of a meaningful interface between the two groups (Oliver et al., 2014).

Organisations such as the National Institute of Health and Care Excellence (NICE) in England and Wales, have provided evidence-based guidance and advice for local policy

makers and practitioners, and offer support on the implementation of recommendations. However, few alcohol prevention programmes have been identified as being effective, and so guidance issued by NICE on school-based alcohol education in 2007 (NICE, 2007) called for partnership working between schools and other stakeholders in efforts to develop actions designed to prevent alcohol misuse by young people. In the UK, schools are the primary setting for delivery of universal alcohol prevention activity (NICE, 2007), although to date there has been limited investigation of the attitudes of educational staff towards the delivery of prevention programmes, or their understanding of the evidence base underpinning such programmes (Van Hout, Foley, McCormack, & Tardif, 2012). Teachers in particular are potentially important providers and gatekeepers (facilitating the use of external providers) for prevention interventions, as in addition to having access to relevant target populations, the classroom is a good environment in which to develop those health-related skills and practices that underpin many prevention programmes (Paakkari, Tynjala, & Kannas, 2010). The relationships built up with pupils over the course of the school year may also support the infusion and reinforcement of prevention messages outside of the timeframe of delivery of an intervention (Bonell et al., 2013; Smith et al., 2004). However, in the busy school environment, and in environments of frequent educational reform and curriculum change, health education and preventive interventions often compete with other timetabled priorities, and delivery is often dependent upon overall school ethos, management decisions, and existing policies on drugs and alcohol. In addition, there is the risk that delivering prevention interventions suggests that the school has a problem with alcohol and drugs, which may affect how the local community perceives the school. Therefore, it is unsurprising that there is little delivery of evidence-based substance use education or prevention

programmes in UK schools (Fletcher, Bonell, & Sorhaindo, 2010; Office for Standards in Education, 2013).

The present study reports data collected as part of the process evaluation component of a large cluster Randomised Controlled Trial (cRCT) that assessed the efficacy of a combined classroom intervention and a parental brief intervention (Steps Towards Alcohol Misuse Prevention Program (STAMPP; ISRCTN47028486)). The parental component of STAMPP was developed by the trial team, delivered at bespoke events in the school setting, and was based on earlier work by Koutakis and colleagues (2008), who found that giving advice to parents about setting strict rules around alcohol consumption reduced drunkenness and delinquency in 13-16 year olds in Sweden (the Örebro Prevention Programme). More specifically, the classroom intervention was an adapted version (McKay, McBride, Sumnall, & Cole, 2012) of the School Health and Alcohol Harm Reduction Project (SHAHRP), a universal school-based program with a psychosocial and developmental orientation (McBride, Farrington, Midford, Meuleners, & Phillips, 2004). It combines a harm reduction philosophy with skills training, education, and activities in order to support positive behavioural change. In the original programme evaluation of SHAHRP in Australia, the intervention was effective (compared with educational as usual) in increasing knowledge and safer attitudes toward alcohol, decreasing alcohol-related harm, and reducing alcohol consumption (McBride et al., 2004). Similar findings were also reported for an adapted version of SHAHRP in Northern Ireland (NI) (McKay et al., 2012).

In this research, we explored how local policy makers (termed 'stakeholders') and senior educational staff in the two trial geographies (i.e. Glasgow/Inverclyde and NI) understood the delivery and implementation of STAMPP and the associated cRCT. The work

also sought to examine how the research design and the evidence it was expected to produce on intervention outcomes was understood, and how the prevention initiatives used in STAMPP corresponded with the development of responses to alcohol at both a strategic (National) and local (Regional and area-based planning) level. Finally, we investigated what conditions would need to be satisfied in order to support the future implementation of STAMPP. We have reported programme recipient (school pupils) responses to STAMPP elsewhere (Harvey, McKay, & Sumnall, 2016), whilst the trial outcomes are currently under review.

Methodology

Recruitment

A total of 105 schools participated in STAMPP. In the present study, purposive sampling was used to ensure that head teachers and/or senior school staff and stakeholders from both participating trial sites (Scotland and NI) and trial arms (head teachers and/or senior staff in Intervention and Control schools) were represented. In this context, 'stakeholders' refers to managers of Educational, Health and Psychological Services in both trial sites, whose remits included strategic planning and operational oversight. The participation of a representative sample ensured that data saturation was achieved and that a variety of perspectives were included.

Interviews

Head teachers and/or senior staff in Intervention and Control schools participated in individual interviews. The purpose of the interviews was to obtain a better understanding of:

(i) how STAMPP, or similar preventative and educational approaches, corresponded with their school's response to alcohol; (ii) how STAMPP might complement the health education that was already being delivered; and (iii) what some of the challenges might be if the programme was shown to be effective and there were opportunities to continue or expand delivery. The aim of STAMPP is to achieve positive behavioural change with respect to alcohol use and is delivered within the complex systems that are schools. Therefore, interviews also sought to understand how those charged with managing schools and/or influencing within-school policies could influence its delivery.

Stakeholders in NI and Scotland with responsibility for policy development and commissioning, participated in individual interviews. Organisational names have been removed to preserve participant anonymity. These interviews examined: (i) how evidence from the STAMPP trial corresponded with current and future intervention delivery and service development strategies; (ii) how STAMPP might complement current approaches; and (iii) what opportunities there would be for future implementation of STAMPP if it was found to be effective. Delivery opportunities (organisational and professional capacities), adherence with target population needs, policy context, implementation processes, and sustainability, and inter-relationships among these components was also explored in the interviews.

Procedure

Participants were invited to take part in an interview by email. The invitation contained information about the purpose of the interview and each individual was asked to indicate if they would be willing to participate. All individuals approached agreed to participate and provided their consent.

The individual interviews were conducted either face to face or by telephone. The mean completion time was 24 minutes, ranging from 10 to 38 minutes. Interviews were recorded and then transcribed by a professional stenographer. Ethical approval for the study was obtained from Liverpool John Moores University Ethics Committee.

Despite the utilisation of the interview guides, question order and wording varied throughout the interviews in order to facilitate the flow of discussion although all pre-determined topics were covered. Extra questions were also included in order to clarify answers or to explore and obtain specific details about discussion points that may have arisen. Statistical analysis of the outcomes of the cRCT had not been undertaken at the time of interview, and so the actual effectiveness (or otherwise) of STAMPP was not used to inform the discussion.

Participants

A total of 27 individuals participated (Male = 13 (48%); Female = 14 (52%)). There were nineteen head teachers and/or senior staff (Male = 9 (47%), Female = 10 (53%)), and eight stakeholders (n = 8; Male = 4 (50%), Female = 4 (50%)). Within NI, there were six head teachers and/or senior staff from intervention schools (n = 6) and eight from control schools (n = 8); while in Scotland, there were three head teachers and/or senior staff from Intervention schools (n = 3) and two from control schools (n = 2). There were four stakeholders based in NI (n = 4) and four based in Scotland (n = 4). The participants did not receive any compensation for participation.

Data Analysis

Interviews were recorded and then transcribed by a professional stenographer. The transcribed interviews were analysed using the procedures described by Braun and Clarke (2006). The procedure involved six steps: (1) familiarisation, (2) generating initial codes, (3) searching for themes, (4) reviewing themes, (5) defining and naming themes, and (6) producing the report. The analysis was conducted by one of the researchers who facilitated the interviews.

Results

Results of interviews with senior staff are presented in four sections, arising from the themes emerging from data analysis (1) *Alcohol and schools*, (2) *Experience of STAMPP delivery and the STAMPP trial*, (3) *Future delivery of STAMPP*, and (4) *Dissemination of STAMPP trial results*. Results of interviews with stakeholders are presented in three sections, namely (5) *Alcohol education in NI and Scotland*, (6) *Evaluation of STAMPP and the STAMPP trial*, and (7) *Future delivery of STAMPP*.

Section 1 School Participants

Alcohol and schools

Alcohol education in all schools had previously been delivered in subjects such as Science, Personal Development, and Personal and Social Education. Topics of education usually focused on disseminating knowledge on the biological consequences of alcohol use and/or the impact that use had on families and social life. The majority of participants

indicated that their schools had developed their own educational resources and assembled materials from a variety of external sources, but not as part of a coherently structured approach. Many held a negative view of available education and resources. The resources were seen as dated, limited, and for students, repetitive; with not enough curriculum time devoted to the subject. Some participants reported that some teaching staff lacked confidence in their ability to deliver alcohol education, primarily due to a lack of training and a perceived lack of expertise. They indicated that they believed in general schools would welcome new and improved resources and training.

It would have been just resources that you would have obtained out of various books that you'd have put together, to create a unit of work for teachers to deliver in the PD [Personal Development] class.

Intervention School, NI

The majority of participants reported that their schools had also utilised the services of outside speakers such as the Police or recovering alcoholics. Some believed that this was a more effective form of delivery than using school staff because outside speakers were generally considered to have greater topic expertise, and students paid more attention to them because of this. On the other hand, other participants were sceptical about the value of outside speakers given that they might be poor speakers and educators, unable to engage with children, and potentially deliver an inappropriate message (in terms of content or agreed approach to alcohol in the school).

Experience of STAMPP delivery and the STAMPP trial

All participants in the Intervention group were pleased that their schools had been randomised to receive the intervention, as this allowed them access to the resources and teacher training available, and to provide pupils with a structured programme. Those in the control group were generally disappointed, as they did not receive these benefits. However, this was mitigated by the belief that they would eventually gain access to training and materials if the programme was shown to be effective, and by an understanding of the research process, in that a control group was an important part of understanding intervention effectiveness. They recognised the value of the research and believed that pupils would benefit in the long-term because of it, a point that was also made by intervention participants.

Participants in control schools reported that they did not have any concerns about participating in the trial for a number of reasons, including a belief that the research was well organised; regular updates about the trial were given; and a belief that participation would have no major impact on school time or resources (intervention schools typically delivered the classroom component during their personal and social development or equivalent classes). Furthermore, those in the intervention group had no concerns about safeguarding issues or the possible damage to the school's reputation if people thought that STAMPP was being delivered in response to specific alcohol-related incidents or concerns in the school.

Intervention participants broadly believed that delivery of the classroom component, SHAHRP, had a positive impact on their students. In their view, it enhanced students' knowledge of alcohol, alcohol use, and associated risks. They believed that the experience of SHAHRP would help students to make informed choices and lead healthier and safer lives. Furthermore, the harm reduction approach of SHAHRP was praised. Other programmes that had promoted abstinence had failed to engage recipients.

We now have a cohort of young people who ... have a good baseline level of knowledge of alcohol and its use, its misuse, the science behind alcohol, units of alcohol ... so they have the tools in order to make positive ... informed choices.

Intervention School, Scotland

Because SHAHRP required delivery across 10 lessons, and over two years, it was viewed positively for its consistency and educational staff believed that by regularly discussing alcohol throughout the course of the programme their pupils were helped to understand that it was acceptable for them to talk about alcohol.

The programme resources were well regarded. The teacher manuals, student workbooks, and CD-ROMs were all praised for their user-friendliness, their attractive layout and the manner in which they made it easy to facilitate, because they contained all the necessary information and consequently a lot of preparation was not required from teachers.

Selecting teachers to deliver SHAHRP did not present any difficulties as it was quite often delivered as part of the health and wellbeing curriculum by teachers with experience of these lessons. These teachers were also frequently the head of year or form teacher and the regular contact that they had with children was seen as beneficial in terms of developing trust and rapport. The teachers were also confident in their ability to deliver SHAHRP as they received training and the resources contained all the information required.

I had all the knowledge at my fingertips, so that was really good. And I also attended the training, which I found very helpful as well. So I felt well equipped to go into the class to speak to them ...

Intervention School, NI

However, a practical issue was that of the time demands of SHAHRP. Some participants had difficulty in implementing it in full. The participants highlighted that they had to ensure that other health and wellbeing priorities such as illegal drug education were also covered. Some participants in control schools also reported that trial data collection (surveys of all participating pupils) initially presented organisational difficulties in terms of arranging a suitable location and time but with experience, this issue was resolved in future waves (there were a total of four data waves).

Future delivery of STAMPP

Future delivery of STAMPP if it is shown to be effective

In general, participants indicated that their schools would be willing to continue or begin delivery of SHAHRP if STAMPP was found to be effective. Those in intervention schools indicated that continued delivery would be supported because SHAHRP was valued with respect to content, the message delivered, and the programme delivery style.

I will continue to use it because I view it ... as a very valuable resource ... These children didn't know prior to this what a unit or two units of alcohol was, and it's not really in ... any of the resources that we have to deliver at the minute.

Intervention School, NI

Senior staff in control schools indicated support of future delivery of SHARHP if it was found to be effective, however, a small number indicated that the decision to begin delivery, even if analysis of the trial showed it to be effective, would also depend on a number of other considerations, including their own within school evaluation of and cost of the resources, and whether there would be curriculum time available.

The participants were asked to indicate if their school would also try to deliver the parental/carer intervention. There were some concerns about poor attendance (overall parental/carer attendance at the school-based parental events was low, around 9% of eligible parents attended, although all received the follow-up information leaflet that reinforced the discussions initiated at the parents meetings), and a perceived lack of skill of some teachers to work with parents, but overall the response was positive and that parents would be appreciative of receiving information and guidance.

Future delivery of STAMPP if it was not shown to be more effective than education as usual

The participants were asked to discuss the potential future delivery of STAMPP, if analyses showed that it was not more effective than education as usual for the overall sample, and if it was shown to be more effective for some subgroups (e.g., unsupervised drinkers, children with a lower SES background). The majority indicated that their schools would support delivery in this scenario; with a small number reporting that such a decision would depend on potential cost implications and availability of time in the pastoral programme, as well as the overall number of students who might potentially benefit. The general view was that it would be worth delivering if it had a positive impact, particularly on those who are most vulnerable. Some participants reported that their school was obliged to work with subgroups and they paid particular attention to providing additional support to those from lower socioeconomic backgrounds.

... we're always looking at initiatives for the lower socioeconomic groups ... And even when you look at Extended Schools funding [a regional programme offering a wide range of services or activities outside of the normal school day to help meet the learning and development needs of pupils, their families and local communities] and

projects that can be implemented that will affect the free school meals children, you're going to get even more support than you would do maybe to other groups.

Control School, NI

The majority of participants indicated that universal delivery would continue even if the programme was not shown to be beneficial for all pupils. Reasons cited for this included the belief that all pupils were entitled to the same education; that even if only a subgroup of students benefited, there would be no negative impact if the other students also received the curriculum; and that within any school class, there would be students with different experiences of alcohol. Targeting students was regarded as something that was difficult to undertake and could potentially stigmatise children. However, it was reported that some students were already being 'targeted' to receive initiatives such as counselling and that they were identified through, for example, social services, self-referral, and/or deterioration in school work.

The participants also discussed the potential future delivery of STAMPP if analysis showed that it was not more effective than education as usual but teachers liked the programme approach and materials. Intervention participants were unanimous in their belief that schools would still continue delivery in this situation, primarily due to their school's positive evaluation and experience of STAMPP. Control participants also, in general, indicated that their schools would begin delivery of STAMPP in similar circumstances. A number of factors influenced their view. For example, if teachers and students liked the programme, in the view of the school this would mean that it was 'effective' at pupil engagement and fulfilling curriculum requirements; if teachers like the systematic approach and materials of SHARHP, they would also be likely to be confident in their ability to deliver it; and schools

welcomed up-to-date resources. However, it is noteworthy that a number of participants from control schools indicated that cost, logistical issues such as teacher training, and the time required to deliver SHAHRP would need to be considered before a decision would be made about delivery in such a situation.

The practicalities of future delivery

Two issues were prominent during this discussion, namely the training of teachers and the acquisition of resources. Teachers are not experts in the subject area and in order for them to feel confident in their ability to deliver SHAHRP and to be engaged in delivery, they require training.

... we're supposed to be so-called "experts" in all the different fields, but I know from personal experience ... that a lot of teachers will kind of stick to what they're confident in, and if they're not confident, they'll avoid it or they'll just skim through it.

Control School, NI

The participants indicated that the cost implications of acquiring resources may present a challenge. It was highlighted that printing costs could be reduced if the resources were presented in an electronic format; a format which schools are already regularly utilising and which are regarded positively by teachers and students. The participants noted that resources would need to be updated when required.

A small number indicated that integrating SHAHRP into their curriculum might be challenging. One participant indicated that the intervention was relatively long (compared with other alcohol education provision) and that their school might develop a condensed

version through informal adaptation and integrate it with other programmes such as drugs education.

Dissemination of STAMPP trial results

Participants indicated that they wish to learn about the results of the trial and the effectiveness (or otherwise) of STAMPP, including its effect on, for example, alcohol-related harm, drinking behaviour, and/or changes in knowledge and attitudes. Two participants elaborated upon why this information may be useful to them. Firstly, those who are delivering STAMPP will want to know if it is supported by research. Secondly, teachers or those who favour the intervention would be able to use this research in their attempts to persuade senior management to utilise it in schools.

It was recommended that the reported data should be school-specific and should reflect the differences between school type (i.e., Catholic vs. State school), the location of the school (i.e., rural vs. urban, NI vs. Scotland), and participant differences (i.e., gender). This was a particular concern in Northern Ireland where a system of academic selection at age 11 persists, and where there exists a greater variation in terms of types of schools (Grammar versus non-Grammar), and geographical location (urban versus rural), compared to the Scottish context. Essentially school-based stakeholders were keen to be assured that any information that would go out to parents would reflect their precise circumstances, and not some overall amalgam of results. A small number of participants believed that research data that did not reflect the characteristics of their school would be of no real interest to them.

... I would question ... for example, attitudes or maybe the age at which maybe boys are beginning to drink, what's happening maybe with our boys here, would that completely or accurately reflect ... what's happening across all of NI ...

Control School, NI

Section 2 Stakeholders

Alcohol Education in NI and Scotland

With respect to addressing alcohol-related issues, there were mixed views among stakeholders in NI on the relative contribution of alcohol prevention curriculums compared to other initiatives such as licensing, marketing regulation, and taxation. Two participants in NI believed that other types of initiatives would have a greater impact on drinking behaviour, with one citing a lack of supporting evidence for the effectiveness of preventative approaches. However, three of the four stakeholders in NI and all those in Scotland indicated that a combined strategy, which includes a prevention component for education, was required. There was a belief that prevention programmes could influence alcohol-related attitudes and norms, which consequentially would impact drinking behaviour

... there's no single way of combating alcohol misuse or drug misuse, and that actually you need to take a broad package approach ... while education in and of itself might not show great impacts, I think it helps set cultural and social norms which could, down the line, change behaviours

Stakeholder, NI

Evaluation of STAMPP and the STAMPP trial

The stakeholders generally agreed that the philosophy underpinning STAMPP complemented their respective alcohol and health policies or strategic priorities for young people. In parts of NI, SHAHRP had already been commissioned under the New Strategic Direction for Alcohol and Drugs Phase II 2011-2016 and has been financially supported by the Public Health Authority (although they generally fund selective rather than universal programmes). According to one stakeholder, SHAHRP was regarded as the “best evidenced” programme implemented in NI. Alcohol education and prevention of misuse and harm were key aims of their alcohol and drug strategy and the harm reduction approach also reflected stakeholder priorities. In Scotland, STAMPP was viewed as a key component in the suite of responses to alcohol. The programme objectives were consistent with local, as well as national strategies to reduce alcohol and drug use by young people. It was also reported that the content of SHAHRP, although similar to that which was already part of the Scottish education curriculum, had a clearer structure and more engaging materials.

The parental component of STAMPP was regarded as a good fit as it had a similar message to the currently funded parental intervention in NI (i.e., Talking to Children About Tough Issues; TATI) in terms of the particular risks associated with unsupervised drinking and the optimal nature of abstinence. However, it should be pointed out that the brief parental intervention used in STAMPP was considerably shorter than TATI (one session, compared to four in TATI). The stakeholder from the DHSSPSNI also reported that they have begun to recognise the potential benefit of intervening with parents.

... the classroom element had been commissioned under that strategy and we did recognise the need to reach outside schools as well and talk to parents. So I do think it fits in within the overall policy and strategy.

Stakeholder, NI

There was agreement among all stakeholders that the inclusion of both a parental and classroom component made STAMPP distinct and some organisations had begun to recognise the potential benefit of intervening with parents.

... the classroom element had been commissioned under that strategy and we did recognise the need to reach outside schools as well and talk to parents. So I do think it fits in within the overall policy and strategy.

Stakeholder, NI

Furthermore, in NI, the utilisation of an educational and skill-development harm reduction approach with the targeted age group rather than an abstinence approach to alcohol was another distinctive characteristic. However, it is was not clear if this approach made SHAHRP distinct in Scotland, with disagreement evident among some stakeholders. It is worth noting that when discussing the cRCT in Scotland, one participant reported that their organisation would be interested in trying to link trial data with other health, wellbeing, and school performance indicators.

Future delivery of STAMPP

Future delivery of STAMPP if it is shown to be effective

The majority of stakeholders indicated that if shown to be effective, colleagues and other stakeholders, policy actions, money and material resources would support future implementation. Evidence-based practice was valued; particularly if teachers delivered it, and some research participants indicated that they would experience pressure from their delivery partners to support implementation if the cRCT reported positive outcomes.

However, support would be contingent upon a number of factors. For example, a stakeholder in NI emphasised that it would depend on how effective STAMPP was in comparison to other programmes that were already delivered. If the intervention was only equally effective, it would be unlikely that the programmes currently delivered would be replaced, due to recommissioning, retraining, and programme costs. This participant was also cognisant that funding cuts to training and resource provision would mean that even if found to be relative more effective, there would still be structural barriers to implementation. In contrast to interviewees from schools, stakeholders also indicated that support for the parental intervention might require further consideration, as in their opinion it would be a challenge to persuade schools to deliver and parents to attend, as well as the potential for difficulties with regards to the provision of funding and resources.

... if it was shown to be effective, the first thing that would strike me would be how effective, and how effective relative to the services and programmes that we already fund. If we were looking at STAMPP showing this was effective but other research showing what we're already funding was equally effective, there'd be no real reason to swap them. But if it was stronger, if it was showing, you know, more effects what we're doing, certainly we would be led by the evidence. Now money and resources is a different question. At the minute, we're facing cuts.

Stakeholder, NI

Future delivery of STAMPP if it is not shown to be more effective than education as usual

The participants were asked to discuss the potential future delivery of STAMPP if analysis showed it was effective in some subgroups, but not the whole population. All

stakeholders indicated that it would be delivered in these circumstances. In Scotland, there was a focus on helping adolescents who are regarded as vulnerable. For example, under the Scottish Attainment Challenge, funding had been provided to effect positive change among vulnerable adolescents.

... if it wasn't that successful overall but it hit the most vulnerable pupils, they would go for it. Because at the moment, there's a thing called the Attainment Challenge in Scotland, which seven authorities have got money and have to effect change for the most vulnerable.

Stakeholder, Scotland

The stakeholders in NI also indicated that their organisations would be supportive of future delivery if effective for subgroups. However, there was a difference in opinion about the manner in which future delivery would take place. One stakeholder from the PHA indicated that because it is difficult to identify individuals in need of help, because they are unlikely to all be in the same setting, and due to the risk of stigmatisation, it would continue to be delivered universally. However, the majority indicated that targeted delivery would take place for cost reasons. It was even suggested that if the intervention is found to be effective overall, but it is significantly more effective for subgroups, it may only be delivered to these in order to attain the greatest return for resources invested.

The participants were asked to discuss potential support if STAMPP was shown to be ineffective, but teachers and pupils reported liking the curriculum. It was recognised that ineffective interventions were not a good use of school time, and there was an opportunity cost with regards to not implementing other approaches.

The practicalities of future delivery

The practicalities that future delivery would entail were discussed. The majority indicated that their primary concern would be poor implementation fidelity. Stakeholders recognised that particular attention is paid to fidelity during an RCT but in the real world, facilitators informally adapt programmes in both planning and delivery. For example, sessions may be removed or condensed to accommodate competing curriculum demands; while if an intervention was subsequently delivered to a targeted subgroup, it might be tailored to suit their needs rather than maintaining programme integrity.

Stakeholders in Scotland highlighted the need for the development of implementation structures for future delivery and warned that not enough attention (in general) was being paid to the “*science behind implementation*” of prevention interventions. If an intervention were introduced into a new location or school, local or school-related factors would need to be taken into consideration.

... that's why lots of ... interventions crash and burn ... there's not enough attention given to the implementation ... in the real world ...they try and transplant that on to a place like the east end of Glasgow [a deprived area of the city]... And there's not enough time given to looking at what's the workforce ... what's the sort of client group ... in terms of children ... what are the outcomes we're looking for ... it can't just be thrown in and expect results in one place that you got in another ...

Stakeholder, Scotland

Discussion

This study explored the experiences and understanding of the delivery of STAMPP, its correspondence with school approaches to alcohol education, and concordance with local alcohol-related public health strategies. The research also sought to explore understanding of the delivery of STAMPP within a cRCT, and how that evidence would be assessed and valued by participants with respect to future alcohol provision.

School-specific factors

Briefly, staff in both intervention and control schools welcomed the research component of the trial and understood the value of their participation. The trial was not overly disruptive to the timetable and intervention school staff believed that the programme had been positively received by pupils. The school curriculum, SHAHRP, was typically delivered in health and social development lessons by teachers of those subjects. Whilst school staff appreciated the availability of a potentially effective structured prevention programme, simple evidence of effectiveness generated by the trial was not the only factor that would determine future delivery. Other considerations included cost, timetable availability, and an understanding of how trial outcomes related to their particular pupils' characteristics and needs. It was also suggested that schools might make adaptations to the structure of the curriculum so that it could be co-delivered with other health education. Of note, both control and intervention school representatives indicated that if staff and pupils enjoyed SHAHRP they would continue delivery regardless of whether it was shown to be effective or not.

Health Service Stakeholders

In contrast to the preferences of school staff, stakeholder decisions on future implementation of STAMPP would be based upon trial results, rather than acceptability to the target group and deliverers. However, education and public health stakeholders held mixed views about the role of prevention programmes in their responses to alcohol. Whilst some questioned the strength of the existing evidence base, others saw school-based prevention as part of a package of activities, that would help form a comprehensive response to alcohol, and viewed the objectives of STAMPP as supporting other local policy priorities, including environmental responses. In the Scottish trial site in particular, there is currently (2016) a focus on the introduction of minimum unit pricing for alcohol, with competing claims, and different evaluations of the applicability of economic modelling data to local contexts being made by advocates, the alcohol industry, and lay populations (Hilton, Wood, Patterson, & Katikireddi, 2014; Lonsdale, Hardcastle, & Hagger, 2012). Similarly, whilst we found that there was a perceived local demand for evidence-based prevention programmes; interviewees with commissioning responsibilities discussed this against backgrounds of reduced budgets, the set-up costs of implementing a new programme, perceived impact (effect size), and the concordance of the aims of STAMPP with the burden of alcohol on local populations. As an example of this, stakeholders expressed a preference for a targeted intervention for higher risk young people, in line with their strategic priorities. Although STAMPP is described as a universal intervention, secondary analyses of earlier implementations of the SHAHRP curriculum component has shown that it may have differential effects in higher risk drinkers, producing greater reductions in the amount of alcohol consumed, the frequency of drinking, and self-reported alcohol related harms than in lower risk drinkers (McBride, Farrington, Midford, Meuleners, & Phillips, 2003; McKay, Sumnall, McBride, & Harvey, 2014). STAMPP may therefore satisfy this requirement, although as discussed by teachers, delivering a

targeted intervention in schools where classes are not typically categorised by health needs will be challenging. Prevention researchers should therefore ensure that their analyses are extended to answer the policy questions that local stakeholders might have, which will only emerge after consultation with them. With a preference within the field for pre-analysis registration of trial protocols (Staessen & Bianchi) it is therefore important that these discussions take place in the early phases of research development.

Future delivery of SHAHRP

During discussions of future delivery of STAMPP some school respondents expressed concern about the length of the programme and whether it could be incorporated into future curriculums. The programme was contrasted with less complex approaches such as single sessions delivered by external providers, and one participant reported that they would consider adapting SHAHRP themselves in order to deliver it alongside illegal drug education. Understanding such potential adaptations is important, because in routine practice, outside of the structures of an RCT, an intervention may not be delivered as intended and formal and informal changes introduced by delivery staff may lead to a loss of programme integrity and unexpected outcomes (Dane & Schneider, 1998; Dusenbury, 2005). Whilst informal adaptation of structured programmes might reflect a lack of knowledge of the concepts underlying prevention activities, it is unrealistic to expect that programme deliverers would not at least wish to adapt structured prevention programmes to suit their own organisational circumstances or the (perceived) needs of their target groups. However, local adaptation is not inevitable, and implementers who have been encouraged to implement programmes as designed through discussions on the importance of programme fidelity are able to do so (Elliott & Mihalic, 2004). Therefore, there is a risk of non-adoption if a programme cannot be

changed to fit the requirements of the practitioner, or if the context of delivery cannot be changed. Adapting a programme might also bring benefits if changes result in, for example, increased target group interest or engagement in the activities. In our interviews, for example, although STAMPP was described as a universal programme, several respondents discussed a preference for targeted approaches based upon delivery to identified sub-groups, or changing of programme content to make it more relevant to those groups.

Factors beyond research 'success'

In their review on research of fidelity of implementation, Dusenbury and colleagues (2005) concluded that researchers should incorporate strategies for increasing the flexibility of programmes without compromising their essential core components. Efficacy trials, such as the STAMPP cRCT should therefore be followed by effectiveness studies which examine programme outcomes in 'typical' conditions (Kam, Greenberg, & Walls, 2003) to better understand adaptations made, although with limited budgets available for prevention research (and respondents identified funding cuts in the interviews) it is uncertain whether local commissioners would have the resources, or time, to wait for the outcomes of such work. However, such studies are essential before disseminating and implementing prevention programmes to scale (e.g. introduction into the curriculum at a national level), and so at the very least, programme mediation analysis should be undertaken in order to better identify core programme components that must be retained for efficacy. (Fairchild & MacKinnon, 2014; MacKinnon & Luecken, 2008)

One noteworthy finding of our research was that school participants reported that they would continue to deliver SHAHRP even if the programme was shown not to be effective. This question did not explore whether this was interpreted by respondents as continued

delivery despite an iatrogenic programme effect (i.e. participation in STAMPP led to increased alcohol use or harm), but does suggest that school staff use different evaluative criteria than researchers and stakeholders when assessing whether to implement a prevention intervention.

Previous research exploring factors determining implementation of school-based substance use prevention programmes has usually focused on organisational or classroom factors, or the skills and competencies required by teachers to deliver them (e.g. Rohrbach, D'Onofrio, Backer, & Montgomery, 1996; Sy & Glanz, 2008; Thaker et al., 2008). Research into the diffusion of health-related interventions in schools more generally suggest that in addition to well characterised personal factors, teachers and other educational staff place less emphasis on programme effectiveness, and more on personal assessments of the degree of compatibility of the programme with their existing values (e.g. what they think 'works', and what they think is the right approach to an issue), past experiences, and practical needs (including being able to use the same teaching strategies that they normally use; amount of preparation required; the clarity of procedural instructions, and the anticipated reception by students) (Bergström et al., 2015; Hallfors & Godette, 2002). Overall, school-prevention programmes that have corresponding characteristics (e.g. pupil engagement) with traditional educational curricula where outcomes are assumed (e.g. exam performance) are much more likely to be adopted (McGrath, Sumnall, Edmonds, McVeigh, & Bellis, 2006; Stead & Angus, 2004; Thurman & Boughelaf, 2015). Unlike countries such as the USA, where a proportion of school funding is dependent upon delivery of effective prevention programmes (Ringwalt et al., 2011) (although few are delivered with fidelity (Hallfors & Godette, 2002)), education providers in the UK are not mandated to provide evidence-based health curricula, and the

quality of delivered universal substance use prevention activities is generally considered to be poor (Fletcher et al., 2010; Office for Standards in Education, 2013).

There are obvious implications for the meaningful relatedness of high-level RCT-type studies and ‘real world’ application. Indeed, it seems difficult to see how concerns around the formulation of a data analysis plan, blinding, and the many other ‘scientific’ issues (pertaining to an RCT) can be reconciled with school-level issues such as timetabling, engagement of children, classroom behaviour, and training of teachers. Some suggestions would be the inclusion of school-based representatives in the drafting of funding applications and trial steering groups, as well as dissemination events wherein researchers could debrief school-based personnel on (simplified versions of) research methods and results. Whilst guidelines and support tools are available, most schools do not have the capacity or capability to identify effective prevention actions (Pankratz, Hallfors, & Cho, 2002; Thurman & Boughelaf, 2015). Further research is therefore needed to better understand strategies to improve the dissemination and uptake of evidence-based prevention practice.

Limitations

The research had several limitations, some of which are described here. Although we believe we had good representation of the relevant stakeholders in the two trial geographies, interviews were conducted with school staff from 19 out of 105 enrolled schools (18.1%). Increasing the sample size may have led to improved representativeness and diversity of views, but our analysis showed concordance of response within those who were questioned, as well as highlighting important areas of disagreement. In addition, STAMPP was unique in that it was the only structured evidence-based alcohol prevention programme that had been delivered in the trial sites in recent years. Although not reported here, other data collected

from pupils and schools suggested provision of usual alcohol education was poor. This meant that participants were not fully able to compare evidence from the STAMPP cRCT or programme implementation with contemporaneous approaches, and comparisons would have been made with informal education provision (e.g. presentations from the police or recovering users), or structural approaches (e.g. alcohol pricing policy) of limited applicability.

Overall the current study indicates that the future development and assessment of prevention interventions should take into consideration the constraints faced by all stakeholders, and in particular those who will eventually deliver the intervention. In particular, the current results indicate that any intervention is likely to be adapted at a local level and so this should be anticipated by designers and factored into their programme.

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