EVALUATION OF A SKILLS-BASED CONDOM INTERVENTION IN AN ALCOHOL-USING STUDENT POPULATION: A FEASIBILITY STUDY

ZOE HURRELL

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Faculty of Health and Applied Sciences, University of the West of England, Bristol

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Part 1: Systematic Review

Are psychosocial-based health interventions effective in encouraging condom use in binge-drinking populations?

Abstract

Rates of sexually transmitted infections (STIs) and unintended pregnancies are high in the United Kingdom. The prevalence of binge-drinking is also particularly high. Alcohol use has been previously implicated in STI diagnoses, as a risk factor for HIV and condom use failures. Condoms remain the mainstay of STI/HIV prevention and are an effective means of contraception. Many interventions exist to encourage condom use and the reasons why condoms are less likely to be used whilst intoxicated have been previously documented. The focus of this review was to determine whether psychosocial based interventions designed to encourage condom use were effective in binge-drinking populations. A systematic search was carried out to identify research in this area and justified parameters of inclusion are described. A total of five articles were included in the review and subject to narrative synthesis. Although studies suggested that the interventions were effective in encouraging condom use in those that drink excessively, internal and external validity were not good across most studies. Conceptual difficulties in establishing "binge-drinking" behaviour as well as methodological difficulties in the execution of the research were identified. However, some interesting findings emerged from this systematic review which point to future avenues of exploration. Although there is evidence to suggest that interventions are effective in encouraging condom use in binge-drinking populations, further research is required addressing the methodological limitations described, as well as focussing on defined binge-drinking populations before a definitive answer can be substantiated.

Introduction

The National Strategy for Sexual Health and HIV (Department of Health, 2001) identifies England as having the highest teenage birth rate in Western Europe as well as rising sexually transmitted infections (STIs) and HIV infections. The strategy aimed to reduce unintended pregnancies as well as the transmission of STIs and HIV whilst ensuring a sound evidence base for HIV/STI prevention over the coming decade. Binge-drinking has been found to be associated with both STIs and unwanted pregnancy (Standerwick *et al.,* 2007). The prevalence of binge-drinking in the UK is also alarming; it has been reported that binge-drinking accounts for 40% of all drinking episodes in men and 22% in women in the UK (Health Development Agency, 2004). Definitions of binge-drinking can vary considerably (Alcohol Concern, 2003) however definitions can be quantitatively based such as that used by the NHS which would suggest men and women drink no more than 8 or 6 units in one session respectively (NHS Choices, 2006) or more qualitatively focused such as that proposed by Murgraff, Parrott and Bennett (1999) who use the term "*risky single-occasion drinking".* This latter definition captures the element of risk often associated with binge-drinking, of which STIs/HIV and pregnancy are but a few. Given the cultural prevalence of binge-drinking in the UK as well as the personal and health costs associated with STI/HIV transmission and unintended pregnancies, exploring the relationship between these phenomena are of particular importance.

A recent review of the literature by Cook and Clark (2005) suggests that out of 11 studies specifying problematic drinking (including binge-drinking or having alcohol-related disorders), 8 found a significant association between alcohol consumption and having at least one STI. The authors comment on the difficulty in conceptualising and measuring problem-drinking

and suggest that future research should employ clearly defined measures of alcohol consumption. More specifically, from a review of studies conducted in Africa, alcohol has been found to be an important risk factor for HIV. Interestingly the authors also report that inconsistent measures of alcohol hinder the generalisability of such research in the field and standardised measures are needed (Fisher, Bang and Kapiga, 2007).

Conceptualising risky drinking represents one of the methodological difficulties in exploring the relationship between alcohol use and unprotected sex. A recent meta-analysis investigated the relationship between the two by using an event-level method; single episodes of sex in regard to alcohol use as opposed to correlating general drinking habits and unprotected sex which can often result in ambiguous data. This approach was thought to aid causal inferences. The results suggested that the relationship between unprotected sex and alcohol use depends on how sexually experienced the individuals are and the context of the relationship (Leigh, 2002). For instance, whilst alcohol may play a role in decreased condom use during first-time sex this association was not observed in recent sexual encounters with regular partners. The likelihood of engaging in unprotected sex is therefore dependent on context as well as alcohol use. Research also suggests that personality characteristics such as sensation-seeking and impulsive decision-making are strongly associated with sexual risk-taking, including alcohol use and failure to use condoms (Donohew *et al.,* 2000).

Using condoms consistently and correctly at every episode of sexual intercourse is an important strategy in reducing the transmission of STIs (Alfonsi and Shlay, 2005) and forms the mainstay of HIV prevention. Condoms are also an important strategy in reducing unintended pregnancy and effectiveness is reported to be 98% (FPA, 2008). Failure to use condoms may be theoretically underpinned by health psychology models. For example,

Sheeran, Abraham and Orbell (1999) found that in a meta-analysis of psychosocial correlates of condom use, attitudes towards condoms, social norms, behavioural intentions and self-efficacy (or perceived behavioural control) were amongst the most important predictors of condom use (such variables are inherent in the social cognition models such as the Theory of Planned Behaviour and the Theory of Reasoned Action). The predictive power of social cognition models, particularly concerning the discrepancy often observed between intentions and behaviour has been previously noted (Sutton, 1998), and the role of alcohol in the case of unprotected sex may be implicated. For example, Brien *et al.* (1994) found that self-efficacy to use condoms was associated with level of alcohol use intensity. More specifically, those who were sporadic users of condoms were less confident in their ability to use condoms when intoxicated. Indeed, the nature of condoms relies on some level of dexterity and merely putting one on may be hampered by high levels of alcohol use. Using alcohol has also been found to hinder safe-sex negotiation skills and increased intention to engage in risky sex (Maisto *et al.,* 2004). Likewise, Simbayi, Kalichman and Jooste (2004) found problem drinking to be associated with condom failures.

The mechanisms behind the link between binge-drinking and unprotected sex have also been explained in terms of an alternative theory. For example, Macdonald, Zanna and Fong, (1994) found that subjects who were intoxicated were more likely to justify sex without a condom than those that were sober. These findings were considered in terms of alcohol myopia which has been previously explored by Steele and Josephs (1990) who report that alcohol causes a myopia, an impairment of thought and perception that results in only the most salient of cues being attended to; the short-term benefits of having sex without a condom are more influential in the decision to engage in unprotected sex than the thought of

contracting a sexually transmitted infection. Further support for these findings and alcohol myopia theory is reported by MacDonald, Zanna and Fong (1996) who found strong evidence from four studies to suggest that alcohol decreases condom use. The results of these studies led the authors to suggest that in order for interventions designed to encourage condom use to work, they must make aware the effects of alcohol on decision making, that interventions should act on peoples "sober" attitudes and that they should encourage people to commit to these decisions before reaching levels of intoxication. They also suggest that if cues promoting condom use were made salient enough, condom use may potentially be increased by alcohol.

Given the evidence presented herein about the high prevalence rates of both binge-drinking, STIs and unintended pregnancies in England, additions to the current literature about the efficacy of safe-sex interventions would be advantageous and in keeping with the National Strategy for Sexual Health and HIV (Department of Health, 2001) objectives. The purpose of this systematic review, therefore, is to establish the effectiveness of interventions in encouraging condom use in binge-drinking populations. This will be done by reporting on the quality of intervention research in this field.

Method

The Cochrane Handbook for Systematic Reviews of Interventions (Higgins and Green, 2008) was consulted at all stages pertaining to the methodology of this review and every effort was made to maintain objectivity and promote a systematic approach in achieving the aims.

Identification of the question

The PICO model (Population, Intervention, Comparison, Outcome) advocated by Booth and Fry-Smith (2004, cited by Pope, Mays and Popay, 2007) was used to refine the research question by breaking down individual components. The population to be focussed on included men and women that binge-drink. The focus on binge-drinking was to differentiate between moderate alcohol use and the more risky features of binge-drinking discussed previously. In terms of types of interventions, it was considered most appropriate to consider all interventions under the umbrella of "psychosocial-based health interventions", thus incorporating the many variations of health education and psychosocial initiatives evident in sexual health research, and more specifically, those interventions designed to encourage condom use. It was not considered appropriate to incorporate a "comparison" as this was not a fundamental aim of the review. The outcome component, however, represents a key feature of this review and this was defined as "condom use". The resulting question forming the basis of this review can be stated as: "Are psychosocial-based health interventions effective in encouraging condom use in binge-drinking populations"?

Search strategy

The PICO model was also used to guide the search strategy. Potential search strategies were piloted and a combination of subject headings and textwords were employed for each PICO element in accordance with Cochrane guidelines. A comprehensive search strategy was devised to cover the three key concepts – 1) Binge-drinking, 2) Psychosocial-based health interventions and 3) Condom use. These three core concepts guided the following Medical

Subject Heading (MeSH) key words to be generated – 1. Interventions, 2. Condom and 3. Binge-drinking. These three terms were exploded to incorporate a wide array of textwords which were combined with the keywords to form the search strategy. Truncation was used to pick up all potential textword endings. Consideration was given to differences in both terminology and spelling between the English language and American English. Boolean operators were used to combine each set of search terms for each concept; all three concepts were then combined together. The PICO model and resulting search strategy can be observed in Appendix A.

A thorough literature search was then conducted to uncover both published and unpublished research in the area of psychosocial-based condom interventions in binge-drinking populations. The following 14 databases were searched specifically for their predominant inclusion of research in the health/social care field; Medline, CINAHL, Embase, Cochrane, PsychInfo, AHMED, NICE, BNI, BioMed, Maternity and Infant Care, Pubmed, Science Direct, Science Citation Index (Web of Science) and Wiley Interscience. In order to promote inclusivity, no date limit was imposed at this stage. In order to address potential publication bias, two key authors of relevant studies were contacted to request grey literature in the field as well as two sexual health organisations and two alcohol organisations based in the UK for relevant research. Hand searches were also carried out from reference lists of key papers.

Inclusion/exclusion process

Following application of the search strategy to all databases, results, in the form of abstracts from this search were imported in to Refworks, a reference management software package.

Once the references gleaned from other sources were also added and duplicates removed, a total of 11, 619 references remained. A breakdown of the number of references obtained from the various sources can be observed in Appendix B. The 11, 619 references were subject to an initial screening process to eliminate those that were completely irrelevant by the author (this included those that were book chapters, animal studies etc). A total of 953 references remained. These abstracts were then reviewed separately by the author and a second marker using a primary set of inclusion criteria;

1. References must be published in English
2. References must include details of an intervention designed to increase/encourage/promote condom use
3. References must refer to an element of alcohol drinking behavior

   (Please note; some abstracts referred to "substance misuse" as opposed to alcohol use, such papers were sought if they fulfilled the other criteria).

To maintain objectivity, the results of this primary screening process were then compared between the author and the second marker. A total of 79 were agreed upon and the full articles for these references were sought. Every effort was made to locate the full articles, however, for pragmatic reasons a cut-off date was imposed, thus articles arriving after this date were not included in subsequent stages. All articles that were successfully obtained were then forwarded to the same second marker with a secondary set of inclusion criteria;

1. Is there a full article to be reviewed in English?
2. Was the paper published during or after 2001?

3. Does the paper describe a psychosocial-based intervention designed to encourage condom use?

4. Does the paper involve an intervention conducted in the Western developed world (including UK, North America, Europe, Australia, Canada and New Zealand)?

5. Does the paper describe a study of prospective/longitudinal design (i.e., does the intervention take place over the forward passage of time and include more than one episode of data collection)?

6. Was condom use reported as an outcome measure?

7. Did part or all of the sample use alcohol in excess during the time in which the intervention took place?

   (Please note that although criterion 3 was stipulated within the primary inclusion criteria it was not always clear from the abstract alone whether the intervention did indeed aim to encourage condom use due to ambiguous terminology. In keeping with the inclusive nature of this review ambiguous references were still sought as full articles).

There are some points to note regarding justification for the secondary inclusion criteria: In order to reflect local population characteristics and facilitate relevance of the research findings to the immediate locale, this review aimed to focus on studies conducted in the Western developed world. Focus was also directed at papers published in or after 2001 (since publication of the Department of Health, 2001 guidelines). In order to gauge the effectiveness of psychosocial interventions aiming to encourage condom use it was

considered most appropriate to consider studies of a prospective/longitudinal design so the potential effects could be seen over a period of time.

The author and the second marker applied these secondary inclusion criteria to the articles, and data were extracted for those that were thought eligible to include in the review (the extraction form for this process including the secondary inclusion criteria can be observed in Appendix C). Any discrepancies at this stage of the process and likewise following application of the primary inclusion criteria were resolved between the author and second marker. The QUORUM flowchart demonstrating the inclusion/exclusion process can be seen in Appendix D. A total of five papers were considered eligible for inclusion in the review.

The data extracted from these five papers forms the basis of the following table (Table 1). Due to the heterogeneity of included studies (particularly concerning study design) it was not considered appropriate to pool the results for meta-analysis, instead, a narrative synthesis was considered most suitable and in-keeping with published guidelines (The Cochrane Handbook for Systematic Reviews of Interventions, Higgins and Green, 2008). The structure of the following narrative synthesis was informed partially by the data extraction form guided by Cochrane in combination with suggestions stated in the 2001 CONSORT Statement (Moher, Schultz and Altman, 2001). Establishing scientific quality was guided by suggested categorisations such as study design, intervention type, content and delivery, participants, measures and analysis. In addition, intervention allocation, blinding and withdrawals were assessed formally using an adapted Jadad scoring instrument (Jadad *et al.,* 1996). This can be observed as well as the resulting breakdown for each of the five studies in Appendix E and F respectively. The overall score for each study is also presented in the following table.

Table 1: Description of studies addressing the effectiveness of condom interventions in those that binge-drink

Article	Study Design/ Length of Follow-up	Intervention	Sample/Setting	Participant Eligibility/ Sample Characteristics	Measures	Analysis	Main Findings/ Sample and Power Calculations	Potential Bias/ Confounding Variables/ Generalisability	Jadad Score (1-5)
Dal Cin *et al.* (2006)	**Study design:** Participants randomised to one of three intervention conditions (control, standard or bracelet) **Length of follow-up:** 5-7 weeks **Number of times data collected:** Twice	**Theory base:** Not explicitly, although guided by alcohol myopia theory **Intervention content:** Video about drink driving (control), video about living with AIDS (standard), video and reminder bracelet (bracelet)	**Source:** University of Waterloo, US **Period of recruitment:** 1999-2003 **Sampling method:** Participants drawn from introductory psychology participant pools **Sample size recruited:** 196 **Sample size used in analysis:** 127 eligible for analysis (2 had engaged in intercourse) 125 used in final analysis **Setting:** Classroom on campus	**Eligibility Criteria:** Participants who had engaged in heterosexual intercourse in the past, used condoms occasionally, consumed alcohol weekly (excluded participants in relationships >1 year) **Characteristics:** Young adults in higher education, 59 men, 137 women, mean age 19.56 years old	**Condom:** Self-reported use of condoms since target date (used to calculate percentage of condom use) **Alcohol:** Participants defined as "intoxicated", information gleaned from self-report	**Analysis:** Two separate analyses of covariance to explore the effect of experimental condition on mean condom use (%) when alcohol consumed and not consumed. Logistic regression analysis examined condom use across 6 groups (experimental condition X reported alcohol use)	**Main findings:** Highest rate of condom use was found in those that had consumed alcohol and were in the bracelet condition (71%) compared to those in the other groups combined (35%, OR=3.90, p=0.05, d=0.36) – condition X alcohol use/non-use **Sample and power calculations:** Not stated	**Potential source of bias:** Demand effects and self-reported data (although dismissed), steps also taken to reduce reporting bias. Experimenters not blinded to intervention condition **Adjustments made for confounding variables:** Not stated **Generalisability:** Possible to generalise value of a reminder cue to other groups of young adults and adolescents	1

Article	Study Design/ Length of Follow-up	Intervention	Sample/ Setting	Participant Eligibility/ Sample Characteristics	Measures	Analysis	Main Findings/ Sample and Power Calculations	Potential Bias/ Confounding Variables/ Generalisability	Jadad Score (1-5)
Celentano *et al.*(2002) **The National Institute of Mental Health (NIMH) Multisite HIV Prevention Trial Group**	**Study design:** Participants randomised to either: Control condition (1 information session) or Intervention condition (7 sessions) **Length of follow-up:** 12 months **Number of times data collected:** 4	**Theory base:** Behavioural Theory –targeted 3 primary factors mediating sexual risk (outcome expectancies, skills and self-efficacy **Intervention content:** Mediating sexual risk, outcome expectancies and self-efficacy, personalising knowledge, recognising change, setting goals, identifying behavioural antecedents, improving skills and trigger awareness	**Source:** STD clinic and health service clients from 7 metropolitan regions in US **Period of recruitment:** Baseline interview to randomisation session = 1 week **Sampling method:** Eligible participants recruited **Sample size recruited:** 3706 **Sample size used in analysis:** 3104 at 12 month assessment (84% retention rate) **Setting:** Not stated	**Eligibility Criteria:** Sexually active, inconsistent condom use last 3 months, recent HIV risk behaviour (sex with new partner, sex with >one partner, sex partner with other sex partners, Tx for STD, at clinic for STD Tx, IVDU, sex with IVDU, HIV+ partner) **Characteristics:** 2/3 were female, 70% non-Hispanic Black, >50% high school graduates, unmarried, unemployed, mostly >25 years	**Condom:** Self-reported condom use at baseline and follow-up/ proportion of intercourse acts in which condoms were used **Alcohol:** Percentage of participants "intoxicated" daily, CAGE score – four-item alcohol abuse screening instrument (reliability/ validity measures not stated)	**Analysis:** Univariate associations between four patterns of sexual risk (protected, improved, relapsed, un-protected or unchanged) Multivariate analysis using stepwise procedure (sig. = p<.1)	**Main findings:** Chi-square (intoxication and sexual behaviour patterns) = 18.27, p<.05, 15.74, p>.05 for intervention and control condition respectively at one year follow-up. 51% and 38% condom use for intervention and control participants respectively. **Sample and power calculations:** Not stated	**Potential source of bias identified:** Not stated **Adjustments made for confounding variables:** Not stated **Generalisability:** Males more likely to demonstrate protected behaviour but higher rate of attrition for men –may limit generalisability	1

Article	Study Design/ Length of Follow-up	Intervention	Sample/Setting	Participant Eligibility/ Sample Characteristics	Measures	Analysis	Main Findings/ Sample and Power Calculations	Potential Bias/ Confounding Variables/ Generalisability	Jadad Score (1-5)
Ingersoll *et al.*(2003) **The Project CHOICES Intervention Research Group**	**Study design:** A multisite single-arm pilot study **Length of follow-up:** 6 months **Number of times data collected:** Twice (baseline and six months post-treatment)	**Theory base:** Motivational interviewing **Intervention content:** 4 MI sessions and 1 contraceptive counselling session	**Source:** Six community settings with high proportions of women at risk of AEP (primary care practice in suburban Florida, urban jail and drug and alcohol centers in Texas, hospital practice in Virginia, US) **Period of recruitment:** Not stated **Sampling method:** Through the media **Sample size recruited:** 190 enrolled **Sample size used in analysis:** 75.3% (143 at follow-up). 59.5% completed all MI sessions **Setting:** Community	**Eligibility Criteria:** Women at risk for AEP (on basis of heavy alcohol use or binge-drinking and lack or ineffective use of contraception), 18-44, not pregnant or planning to be, fertile, sex with non-sterile man in previous 6 months **Characteristics:** 37.4% white, 45.3% non-Hispanic black, mean age 30.9, 77.4% minimum high school education	**Condom:** Use reported as percentage at baseline and then combined with contraceptive pill at follow-up and presented as over all percentage **Alcohol:** Frequency, quantity and bingeing (>7 drinks per week, 5 or more drinks in a single day). AUDIT tool	**Analysis:** X^2 and t-tests to identify differences between those who completed follow-up and those that did not. Bivariate logistic regressions used to identify predictors of outcome	**Main findings:** 85% of sample using mostly condoms or contraceptive pills consistently at follow-up (not individually reported) compared to 53.2% and 17.4% using condoms and contraceptive pills in-consistently at baseline **Sample and power calculations:** Not stated	**Potential source of bias:** Not an RCT, self-reported data (social desirability/effect of paid expenses), only 59.5% of sample attended all 4 MI sessions **Adjustments made for confounding variables:** Not stated **Generalisability:** Not stated	1

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LaBrie *et al.* (2008)	**Study design:** Participants randomly assigned to safer-sex or alcohol targeted intervention (within subjects design and no true control group) **Length of follow-up:** 30 days **Number of times data collected:** 3 times (pre and post intervention and follow-up). Behavioural measures collected pre intervention and at follow-up	**Theory base:** Motivational interviewing particularly decisional balance component **Intervention content:** The decisional balance in non-confrontational style and non-judgemental style consistent with MI to promote condom use	**Source:** West coast university **Period of recruitment:** Not stated **Sampling method:** Flyers posted in academic buildings and halls of residence **Sample size recruited:** 90 (43 men in safer-sex intervention, 47 in alcohol targeted intervention – the latter has been written up elsewhere) **Sample size used in analysis:** 43 men in safer sex intervention, 41 completed intervention and 37 completed 30 day behavioural log **Setting:** University	**Eligibility Criteria:** Participants identified as at-risk (drinking more than twice a week and who had intercourse (vaginal or anal) with two or more heterosexual partners in previous two months **Characteristics:** High-risk heterosexual college men, average age of 20.56 years, 76% Caucasian	**Condom:** Self-reported condom use presented as percentages. Adapted RTCQ (motivation to use condoms); α=.84, condom use ruler, TLFB-SS for sexual behaviour (no reliability reported) **Alcohol:** RTCQ (motivation to reduce drinking); α=0.72. TLFB-SS to assess retrospective drinking (number of drinking days and number of drinks consumed) –no reliability reported	**Analysis:** Within subjects paired samples t-tests were used for behavior change measures	**Main findings:** Condom use increased from 41% pre-intervention to 70% at follow-up $t=(35)=4.23$, $p<0.001$, $d=0.85$ **Sample and power calculations:** Not stated	**Potential source of bias:** Self-reporting bias dismissed as TLFB-SS did not demonstrate decrease in alcohol as one might expect although still relies heavily on self-reported retrospective behaviour. No true control group **Adjustments made for confounding variables:** Not stated **Generalisability:** Limited by exclusion of women, bisexual and homosexual men. Not ethnically representative. Limited by short follow-up period.	1

Article	Study Design/ Length of follow-up	Intervention	Sample/ Setting	Participant Eligibility/ Sample Characteristics	Measures	Analysis	Main Findings/ Sample and Power Calculations	Potential Bias/ Confounding Variables/ Generalisability	Jadad Score (1-5)
Jemmott *et al.* (2005)	**Study design:** Randomised controlled trial (randomised by computer generated number sequences) **Length of follow-up:** 12 months **Number of times data collected:** 4	**Theory base:** Based on CBT and formative research and incorporating variables from TRA, TPB, and social cognition theory **Intervention content:** Skills based HIV/STD intervention, information based intervention or health promotion control intervention. Each intervention lasted 250 minutes and included information, discussions, videos and	**Source:** Family planning patients at adolescent medicine clinic in children's hospital in Philadelphia, US **Period of recruitment:** Not stated **Sampling method:** Eligible participants volunteered to take part after being informed of study during bi-annual STD screening visit **Sample size recruited:** 682 (219 control, 228 information intervention, 235 skills based intervention) **Sample size used in analysis:** 604	**Eligibility Criteria:** Participants had to be patients at the adolescent clinic, sexually experienced, not pregnant, 12-19 years old, able to read and speak English, didn't plan to move. Some mothers of participants also took part (mothers' randomisation took place independently of daughters randomization - this part of the study is written up elsewhere - not stated) **Characteristics:** 463 African American and 219 Latino	**Condom:** Number of days participant reported having unprotected sex in last 3 months **Alcohol:** Participant defined as being "high on drugs or alcohol" or "intoxicated"	**Analysis:** Poisson regression analyses, analysis of covariance, logistical regression analyses	**Main findings:** Skills based intervention resulted in less unprotected sex whilst intoxicated, d=0.20, p=0.02 **Sample and power calculations:** A sample of 506 participants was expected to yield 80% power to detect a 0.25-SD difference (α=.05, 2-tailed) in self-reported frequency of unprotected sex	**Potential source of bias:** Self-report (although biological outcomes were also collected from STD screening. Clinicians and questionnaire proctors were blind to intervention type). Steps taken to reduce reporting bias **Adjustments made for confounding variables:** No **Generalisability:** Sample were African American or Latino girls thus unknown whether same findings would be generated from a different sample. As RCT was single session everyone got the same amount of input, only content varied	3

		games. Skill based arm included practical condom use skills using anatomical models, condom use negotiation (role-playing) and barriers such as alcohol	completed at 12 months (199 control, 196 information intervention, 209 skills based intervention). 88.6% retention rate at 12 months **Setting:** Children's hospital (sample source)	adolescent girls (12-19 years)			(controlled for Hawthorn Effect). Non-returners were more likely to have unprotected sex while intoxicated than returners

Results

Study design

Four out of the five studies employed some kind of randomisation to conditions, although only Jemmott *et al.* (2005) identified their study as being a RCT, assigning participants to 1 of 3 interventions (skills-based, information-based and a health promotion control condition). Participants were assigned on the basis of computer-generated random number sequences undertaken by one researcher. This represents one of the fundamental differences between studies regarding the Jadad score as this was the only study to randomise appropriately (please see Appendix E for a definition). Dal Cin *et al.* (2006) randomised participants to one of three conditions (control, standard or bracelet) although this process involved blocking groups and likewise Celentano *et al.* (2002) randomly assigned participants to the control condition (which involved one information session) or to the intervention condition (which involved 7 sessions) on the basis of participants arriving in blocks of ten. LaBrie *et al.* (2008) randomly assigned participants to a safer-sex intervention or an alcohol targeted intervention with no true control group and no information was given to suggest how this was done. This study was of a within-subjects design although only the safe-sex intervention was presented in the paper. Ingersoll *et al.* (2003) represent the biggest deviation in terms of study design (contributing to the observed heterogeneity of studies) in that they conducted a multisite single-arm pilot study.

The length of follow-up varied between studies from 30 days (La Brie *et al.,* 2008) to 12 months (Celentano *et al.,* 2002 and Jemmott *et al.,* 2005). The number of times that data was collected also varied between studies, from two (baseline to follow-up, Ingersoll *et al.,* 2003) to four (Celentano *et al.,* 2002, Jemmott *et al.,* 2005). Baseline measures were obtained by

Jemmott *et al.* (2005), Ingersoll *et al.* (2003), Celentano *et al.* (2002) and LaBrie *et al.* (2008). Although Dal Cin *et al.* (2006) collected data at two time-points, (participant responses immediately post-intervention and outcome measures at follow-up) they did not provide adequate baseline measures (interpretation of the results in light of this will be considered later). On the strength of these issues, the Jemmott *et al.* (2005) study therefore demonstrates the most robust study design.

Intervention type: Theoretical underpinning

Interventions were theoretically underpinned, however the extent to which these were elaborated on varied between studies. Two studies employed motivational interviewing (MI) strategies; LaBrie *et al.* (2008) and Ingersoll *et al.* (2003), (the former focussing particularly on one element of MI – the decisional balance, which was comprehensively explained and the latter encompassing a contraception counselling session). It is also important to note that as Ingersoll *et al.* (2003) were focussing on reducing alcohol exposed pregnancies (AEPs) there was a dual focus to the intervention; reducing alcohol and encouraging contraceptive behaviours (which was not as thoroughly described). Celentano *et al.* (2002) based their intervention on behavioural theory and targeted three primary facets - outcome expectancies, self-efficacy and skills, backed up by frequent references. Jemmott *et al.* (2005) based their intervention on cognitive behavioural theory (CBT), formative research and also incorporated variables from the Theory of Reasoned Action, the Theory of Planned Behaviour and Social Cognitive Theory (although the rationale behind these decisions was not explicit). The theory behind the paper presented by Dal Cin *et al.* (2006) was not overtly evident although reference was made to alcohol myopia theory.

Content

The content of each study pertaining to condom promotion in heavy alcohol users varied considerably between studies. The focus of the Dal Cin *et al.* (2006) intervention was to see if the use of a reminder cue (a bracelet) could increase condom use following a safe-sex intervention by increasing the salience of the safe-sex message. A secondary aim of this investigation was to see if this effect would still be observed under the influence of alcohol. The intervention content of the Celentano *et al.* (2002) study involved a number of safe-sex strategies including condom use skills with a focus on HIV prevention. The focus of the Ingersoll *et al.* (2003) study was on reducing AEP and thus concentrated on methods of contraception, of which condoms were one, in conjunction with reducing alcohol intake. Jemmott *et al.* (2005) considered HIV risk reduction of which condom use was a major contributor. Both the information and skills-based interventions included the importance of using condoms although the skills-based condition included condom use negotiation skills using role play and also involved putting them on to anatomical models whilst addressing barriers to condom use including alcohol use. The control condition was designed to be as enjoyable and informative (although not with a HIV focus) in order to control for Hawthorne effects. LaBrie *et al.* (2008) investigated the effectiveness of the decisional balance in increasing motivation to use condoms and actual condom use, in an alcohol using population by generating lists of reasons to use condoms and exploring reasons for change. Participants were then required to fill in a 30 day behavioural log including sexual activity, condom use and alcohol consumption. In determining how useful these studies are in considering the effectiveness of condom interventions in binge-drinking populations, one must logically be guided by the content pertaining to *both* condom and alcohol use. On the strength of the

evidence presented, this would suggest that the studies by LaBrie *et al.* (2008) and Dal Cin *et al.* (2006) were best placed to do this.

Delivery

Delivery of the interventions across studies was reasonably consistent with the majority being delivered by trained or experienced personnel with the exception of the Dal Cin *et al.* (2006) study. Generally, attempts were made to keep the demographics of the facilitators/interviewers in keeping with the participants involved with the study (i.e., male, MI trainers for LaBrie *et al.,* 2008 and African-American female facilitators for Jemmott *et al.,* 2005). It is not entirely clear from the write-up in what contexts interventions were delivered. No study identified explicitly as being "double-blind" (accounting for low Jadad scores), although the Jemmott *et al.* (2005) study did report both questionnaire proctors and clinicians were blind to participants intervention assignment. This would suggest that this study, again, demonstrates superior execution.

Sampling and participants

The period of recruitment was not reported for any studies with the exception of Dal Cin *et al.* (2006) that suggested that participants were recruited over a four year period drawing from a pool of psychology students. The sources of sample populations varied between studies which is likely to inform the generalisability of findings (to be discussed later). Two studies made use of student populations (Dal Cin *et al.,* 2006 and LaBrie *et al.,* 2008). In both

cases the intervention also took place on campus. Jemmott *et al.* (2005) recruited participants from a children's hospital (which also formed the setting of the intervention). Both Celentano *et al.* (2002) and Ingersoll *et al.* (2003) recruited participants from a range of community and health settings, with the latter targeting women at high-risk of an AEP (including prison and alcohol centres). In both cases, participants were drawn from a wide geographical area). It is not clear where Celentano *et al.* (2002) conducted their study although Ingersoll *et al.* (2003) suggest theirs took place in community settings.

Information regarding sampling methods often linked to the individual study's eligibility criteria and for most studies this involved participants being deemed as at-risk from either unprotected sex or excessive drinking or both. Celentano *et al.* (2002) considered participants eligible for inclusion if they were sexually active, used condoms inconsistently in the previous three months or demonstrated a range of risky sexual behaviours. The participants in the Jemmott *et al.* (2005) study were required to be sexually active, although not pregnant, adolescent girls. The remaining studies required alcohol and sexual risk criteria to be fulfilled. Ingersoll *et al.* (2003) required participants to be at-risk for AEP thus participants had to be heavy or binge-drinkers using no or ineffective contraception, fertile and previously sexually active with a non-sterile man. Likewise, both Dal Cin *et al.* (2006) and LaBrie *et al.* (2008) required participants to have engaged in heterosexual sex and to consume alcohol regularly or in a risky manner.

The sample characteristics differed between studies and were related to sample source or eligibility criteria. Dal Cin *et al.* (2006) investigated college age young adults as did LaBrie *et al.* (2008), although the latter employed only male and predominantly white participants. Conversely, those involved in the Jemmott *et al.* (2005) study were African-American and

Latino 12- to 19-year old girls. The participants from the Ingersoll *et al.* (2003) and Celentano *et al.* (2002) study were relatively similar, mainly high-school educated, black participants drawn from low socioeconomic community settings.

Sample sizes were reasonable and information regarding attrition was good across studies (please see Jadad scoring, Appendix F). The largest sample was that used in the Celentano *et al.* (2002) study with 3704 recruited and 3104 at 12 month follow-up used in analysis (an 84% retention rate). Analysis revealed that socio-demographic data remained largely unchanged from recruitment to follow-up with the largest predictors of attrition being age (<35 years), study site and men recruited from sexual health clinics. Ingersoll *et al.* (2003) recruited 190 participants with 143 completing the follow-up period (a retention rate of 75.3%). Whilst this seems reasonable, on closer inspection only 59.5% attended all four MI sessions and only 62.1% participants attended the contraceptive counselling session. Thus although three quarters of the sample responded at 6 month follow-up a sizeable proportion of the sample had not received the intervention in full although the authors suggest that the success of the intervention was not dependent on the women completing all sessions and they also reported that there were no significant differences found between those that completed follow-up and those that did not. Retention rates were also reasonable within the Jemmott *et al.* study (2005) with a total of 682 being recruited (219 to the control condition, 228 to the information intervention and 235 to the skills-based intervention) versus 604 completing the study after 12 months (199, 196, and 209 respectively). This meant that there was an 88.6% retention rate at 12 month follow-up. Analysis revealed that attendees differed from non-attendees in that the latter reported more unprotected sex while intoxicated which may obviously affect this study's ability to answer the question inherent in this systematic review.

The retention rate in the Dal Cin *et al.* (2006) study was relatively poor with 196 initially recruited and 127 returning for follow-up 7 weeks later (125 eligible to be included in analysis). The sample used in the LaBrie *et al.* (2008) study was relatively small but the retention rate was fair, 43 men being assigned to the safer sex intervention and 47 being assigned to the alcohol condition (41 of the former completing the intervention and 37 attending the follow-up 30 days post-intervention). No significant differences were found between those that completed the behavioural log and those that did not. Therefore although the Jemmott *et al.* (2005) study demonstrates the least attrition with the greatest follow-up period, generalisability of findings may be compromised by discrepancies between those that completed follow-up and those that did not.

Measures

The focus of this review is the effectiveness of psychosocial based interventions aimed at encouraging condom use in binge-drinking populations and to that end this review will focus on measures used to capture condom use and binge-drinking. Measures for these concepts involved almost exclusively relying on participants self-reports, the only exception being the Jemmott *et al.* (2005) study which employed biologically confirmed screening for STIs as a secondary outcome measure.

Condom use was typically measured at baseline and as an outcome measure and presented as a percentage, however, whilst, Dal Cin *et al.* (2006) required participants to be occasional users of condoms no firm reporting of this was given at baseline. Although Ingersoll *et al.* (2003) reported condom use as a percentage at baseline they combined this percentage at

follow-up with use of the contraceptive pill thus an individual breakdown was not provided for condom use alone. In addition to percentages of condom use at baseline and follow-up, LaBrie *et al.* (2008) also included intention and motivation to use condoms at baseline and follow-up (considered to be a good predictor of future condom use using the adapted Readiness To Change Questionnaire [RTCQ], $\alpha = 0.84$). Most notably, they employed the Timeline Followback Interview: Sexual behaviour and substance use (TFLB-SS) – a tool for assessing retrospective drinking and sexual behaviour although no reliability was reported for this measure. Celentano *et al.* (2002) grouped participants at follow-up in to four categories based on percentages of condom use (protected, improved, relapsed or unprotected). Jemmott *et al.* (2005) although using condom use as the primary outcome measure, captured this data by presenting it as the number of days participants engaged in un/protected sex at baseline and at later follow-up sessions.

The measures used to define alcohol use also relied upon self-reported data at both baseline and follow-up, the differences between studies hinging on conceptualisations of heavy, regular or binge drinking patterns and whether alcohol was measured in isolation or as part of sexual behaviour. Jemmott *et al.* (2005) for example, considered the number of days that participants engaged in sexual intercourse whilst "high" on alcohol or drugs – combining alcohol and drugs together thus also has implications for the aims of this review as determining whether or not this intervention was effective under the influence of alcohol is not explicitly clear. Celentano *et al.* (2002) employed use of the CAGE drinking assessment tool although no reference was given to the reliability of this measure. They also conceptualised drinking in terms of "intoxication" daily or more than once per week, once a week or less or never. Ingersoll *et al.* (2003) also employed a measure of alcohol use, in this

case the AUDIT tool, although again, no reliability was reported. This study however, contained a firm definition of binge-drinking classified as five or more drinks per day and frequent drinking identified as more than seven drinks per week. As with condom use, LaBrie *et al.* (2008) considered intention and motivation to drink alcohol (using the RTCQ, $\alpha = 0.72$) at baseline and follow-up in conjunction with drinks per month, number of drinking days and drinks per occasion, thus going some way to establishing differentiations between risky and moderate drinking. As mentioned, the TFLB-SS was used to assess drinking behaviour (no reliability reported). Again, with alcohol use, Dal Cin *et al.* (2006) reported no firm measures of alcohol use at baseline although did report alcohol use as a percentage at follow-up. On the strength of this evidence in addressing the aims of this review one could therefore consider the LaBrie *et al.* (2008) study most well-equipped to measure alcohol and condom use.

Analysis and main findings

The statistical methods employed by the researchers of each study appear to be appropriate regarding the methodology employed however, the reporting of results varied considerably; studies typically reported (p) values but no confidence intervals. No retrospective power calculations were explicitly stated.

Only Jemmott *et al.* (2005) reported a prospective sample-size calculation – the power of the study was estimated to be 80% to detect an effect size of 0.25 given that α was set at 0.05 with an anticipated sample size of 506 participants regarding the self-reported frequency of unprotected sex between the conditions. Effect sizes (*d*) were also presented for each

significant contrast. For the purposes of this review, the main findings were that the skills-based intervention produced less self-reports of sex whilst intoxicated than the health promotion control condition (*d*=0.18, p=.03) and the information only condition (*d*=0.18, p=0.03) at the three month follow-up in comparison to the control condition at the six month follow-up (*d*=0.23, p=0.005). Most importantly, the skills-based intervention resulted in less self-reports of unprotected sex whilst intoxicated (*d*=0.20, p=0.02). LaBrie *et al.* (2008) also reported effect sizes (Cohen's *d*); condom use increasing from 41% pre-intervention to 70% at follow-up (*t*= (35) = 4.23, p<0.001 and yielding an effect size of *d*=0.85). Dal Cin *et al.* (2006) also reported effect sizes; the most relevant findings reported were that when alcohol had not been consumed, mean condom use across conditions was 42% versus 47% when alcohol had been consumed. The bracelet (reminder cue condition) yielded the highest rate of condom use (60%) compared to the standard condition (39%) and control condition (42%), t (72) = 3.20, p< 0.01, *d*=0.75. More specifically, the highest rate of condom use was observed in those that had consumed alcohol and were in the bracelet condition (71%) compared with the five other groups combined (35%, OR = 3.90, p=0.05, *d*=0.36) – condition (bracelet, control, standard) x alcohol (use or non-use). Celentano *et al.* (2002) reported that chi-square analyses revealed a strong relationship between alcohol intoxication and sexual behaviour patterns at one-year follow up 18.27, p<0.05 and 15.74, p>0.05 for the intervention and control conditions respectively. Ingersoll *et al.* (2003) reported condom use in terms of percentages pre and post intervention; 85% of the sample using mostly condoms or contraceptive pills consistently at follow-up (not individually reported) compared to 53.2% and 17.4% using condoms and contraceptive pills inconsistently at baseline. Reporting combined use of condoms and contraceptive pills at follow-up has implications for the

usefulness of this data in light of the reviews aims. On the strength of the evidence provided it would seem justified to consider the presentation of results more reliable for the Jemmott *et al.* study (2005), although how useful these results are in addressing the aims of this review is limited. In contrast, the results yielded from the Dal Cin *et al.* (2006) and LaBrie *et al.* (2008) studies are the most relevant in answering the review question but how dependable these results are is ambiguous.

Discussion

Internal validity

Before considering the generalisability (external validity) of research findings, it is first necessary to consider what studies demonstrate internal validity. The reporting of potential sources of bias differed between studies and it is worth noting that although studies may not have reported on sources of potential bias this does not necessarily mean that there were none.

Four of the studies involved some kind of randomisation procedure although only Jemmott *et al.* (2005) self-identified as being an RCT. Indeed, the procedure for this study was more true to randomisation than the others (please note the Jadad score). Equipoise, however, was not discussed. Adjustments made for confounding variables were not discussed across studies and only a couple of studies considered the effects of blinding (Dal Cin *et al.,* 2006 and Jemmott *et al.,* 2005), although only the latter actively took steps to blind (although not explicitly stating the study as double blind as evidenced by Jadad scoring). Data collection methods involved almost exclusively self-reported data about condom and alcohol use which

intuitively is subject to both recall issues as well as demand effects in terms of reporting bias. Steps taken to reduce this potential effect were reported by Jemmott *et al.* (2005), Dal Cin *et al.* (2006) and La Brie *et al.* (2008). Attrition varied between studies although this was a particular issue for Dal Cin *et al.* (2006) and for Celentano *et al.* (2002) who found that although male participants demonstrated higher levels of protected behaviour following the intervention, they also demonstrated a higher level of attrition. It is also worth noting that only just over half of the sample in the Ingersoll *et al.* (2003) study completed the entire MI component of the intervention. Special consideration was given, however, to examining differences between completers and non-completers in the absence of a RCT design. Whilst there appears to be no obvious source of bias in the analyses across studies, intervention integrity and the effects of contamination are of particular concern with the Celentano *et al.* (2002) study in that there was a large discrepancy between the intervention conditions. Whereas the control condition involved just one session, the intervention session involved 7 sessions – any effects observed from the intervention condition could potentially be due simply to elevated levels of attention or interaction (the Hawthorne Effect). Some studies made efforts to reduce such effects by engineering intervention conditions to be similar in terms of number and length of sessions (Jemmott *et al.,* 2005 and Dal Cin *et al.,* 2006).

Generalisability of findings (external validity)

In line with recommendations, (The Cochrane Handbook for Systematic Reviews of Interventions, Higgins and Green, 2008), only studies with demonstrable internal validity should be considered for generalisability. Within the context of this review this would appear

to be the study presented by Jemmott *et al.* (2005). The scientific quality assessed from both the Jadad score and this narrative synthesis indicates that this study demonstrated superior design, execution and presentation of results. The most prominent factor in assessing the extent to which the results of this study can be applied to the wider population involves the sample employed. Although adolescent girls of African American or Latino ethnicity may represent a group at risk of unprotected sex in metropolitan America, the extent to which these findings can be related to the local population of this review may be limited. It is also worth noting that other populations such as men that have sex with men (MSM) represent a group at high-risk of both STI/HIV transmission through sexual practices and substance use (Davidson *et al.,* 1992) which Jemmott *et al.* (2005) did not include. Another consideration to note with this study regarding applicability of the findings is that attendees differed from non-attendees in that the latter reported more unprotected sex while intoxicated. This finding has particular ramifications pertaining to the aim of this systematic review.

What interventions report effectiveness in encouraging condom use in binge-drinking populations and can we trust the results?

The results of Jemmott *et al.* (2005), LaBrie *et al.* (2008) and Dal Cin *et al.* (2006) studies in particular suggest that interventions can be successful in encouraging condom-use in those that binge-drink. The assessed scientific quality of these studies employing the Jadad and narrative synthesis however, renders the results of the latter two studies less reliable than the former. Thus although the results from the Dal Cin *et al.* (2006) study suggest that condom use can be promoted in student populations intoxicated with alcohol by employing a

reminder cue bracelet, there are methodological shortcomings which compromise the strength of this evidence. The most significant limitation is the lack of true baseline measures, further exacerbated by short follow-up period, inappropriate randomisation, lack of blinding and poor retention rate. Failure to adequately define binge-drinking also limits applicability of these results pertaining to this review. The LaBrie *et al.* (2008) study demonstrated more comprehensive measures and definitions of alcohol use and employing an event-level inspired log equips this study to address the aims of this review more adequately. This study therefore presents reasonable evidence to suggest that an MI approach to encouraging condom use is effective in male, predominantly white student populations. Again, however, the strength of this evidence is hampered by a short-follow up period, inappropriate randomisation and no true control group.

As demonstrated by the Jadad scores and narrative synthesis regarding the Jemmott *et al.* (2005) study, there is good evidence that skills-based interventions to encourage condom use are effective in adolescent girls when intoxicated with alcohol or drugs. The results of this study are more trustworthy than the others considered in this review. This was the only study to truly randomise participants, actively blind investigators to participants' intervention assignment, collect biologically confirmed STI data or consider sample-size calculations. The length of follow-up and retention was also good. The generalisability of these findings is limited by sample characteristics and the reported discrepancies between attendees and non-attendees as discussed and it is important to remember that drug and alcohol intoxication was considered together in this study. Whilst this fits with previous research to suggest that sexual risk-taking often occurs alongside drug and alcohol use in high-risk individuals (Donohew *et al.,* 2000), establishing, definitively, whether this intervention is

effective in those that binge-drink as opposed to those that use alcohol and drugs simultaneously to the point of intoxication is therefore inconclusive. Nonetheless, this study presents good evidence to suggest that condom use can be increased whilst *intoxicated* by implementing a single skills-based intervention session focussing on role-playing, condom negotiation and practicing condom use.

Considerations for future research

As the Jadad scoring would suggest, the research quality of studies included in this review was generally poor and hampered by methodological difficulties particularly concerning conceptualising binge-drinking and condom use. Future research should address these limitations if a definitive answer to the review question is to be found.

Although all studies reported participants' excessive alcohol use, there were certain difficulties defining and conceptualising this. This finding echoes the previous suggestions of Fisher, Bang and Kapiga (2007) and Cook and Clarke (2005). Jemmott *et al.* (2005) and Dal Cin *et al.* (2006) for instance refer to their sample as being "intoxicated" (with drugs and alcohol being considered together in the former study and binge-drinking not being defined in either *per se*). Thus it is difficult to ascertain the extent and pattern of the participants' drinking habits. It is also important to note that most studies are unable to report whether condoms were used *while* participants were binge-drinking. This limitation lends support to event-level studies described earlier (Leigh, 2002) and the log approach employed by LaBrie *et al.* (2008).

The disparity that existed between studies regarding measures is testament to the difficulties involved with investigating sexual and alcohol behaviours. However, although a challenging

area of research many studies exacerbated these issues by unclear or incomplete methods of reporting. The reliance on self-report is possibly unavoidable in the arena of alcohol and sexual behaviour research however, the lack of recognised measures and the omissions related to the reporting of reliability compromises research quality.

The content of future condom interventions directed towards binge-drinking populations can be informed by the findings of this review. For example, the results of the Dal Cin *et al.* (2006) study are intriguing; the suggestion that condom use may be increased by drinking alcohol if the cues to promote safe-sex were made salient enough (consistent with the previous assertions of MacDonald, Zanna and Fong, 1996) poses an avenue for future research. Likewise, the use of a log and an MI approach to facilitating condom use reported by LaBrie *et al.* (2008) is also worthy of future investigation. In both cases, however, the methodological drawbacks and difficulties conceptualising condom and alcohol use needs to be addressed. The practical, skills-based approach adopted by Jemmott *et al.* (2005) applied to a specific binge-drinking population would also provide an excellent opportunity to address the aims of this review.

Conclusion

The small number of studies included in this review, despite a systematic search is surprising given the prevalence of both binge-drinking and the negative consequences of unprotected sex. This review however, was limited by the focus on quantitative research, published since 2001 and conducted in the Western world. This review has revealed that there is a lack of good quality research in this area. The study presenting the most superior research is unable

to definitively address the aims of this review due to combining alcohol and drug use together. This review also highlights the methodological difficulties involved in researching this area, particularly defining and measuring binge-drinking and investigating the context of sexual relationships. The need for reliable measures and a robust study design is paramount if this field of research is to progress. In terms of addressing the aims of this review, interventions do appear to encourage condom use in binge-drinking populations; there is however, a need for better quality research in this area for this to be truly substantiated.

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Appendix A: SR Question and Search Strategy

Population: Men or women that binge drink.

Intervention: Psychosocial interventions designed to encourage condom use

Comparison: No comparison with other populations

Outcome: Condom-use

Question: "Are psychosocial-based health interventions effective encouraging condom use in binge-drinking populations?"

The SR will search for: Papers documenting health interventions designed to promote/increase/encourage condom-use. This Systematic Review will focus on whether these interventions were effective in increasing/promoting/encouraging condom-use in those that binge-drink

MeSH Subject Headings and Key Words:

Binge drinking: Alcohol drinking, alcoholic intoxication, ethanol, alcoholism, adult, adolescent, students, kidney failure (acute), accidents (traffic), alcohol related disorders. *Binge drinking.mp. as keyword.*

Intervention: Crisis intervention, early intervention, intervention studies. *Interventions.mp as keyword.*

Condoms: Condom. *Condom.mp.as keyword*

Search terms*:

- "binge drink*" **OR** drink* **OR** alcohol* **OR** "problem drink*" **OR** "hazardous drink*" **OR** "social drink*" **OR** "underage drink*" **OR** ethanol **OR** adult* **OR** adolescent* **OR** student* **OR** "acute kidney failure" **OR** "traffic accident*" **OR** intoxicat*

AND

- interven* **OR** "public health" **OR** "client education*" **OR** "health attitude*" **OR** "health behavio?r*" **OR** "health education*" **OR** "health knowledge" **OR** "health maintenance organi?ation*" **OR** "health screening" **OR** "lifestyle change*" **OR** "preventative medicine" **OR** "social marketing" **OR** "health initiative*" **OR** "health promot*" **OR** "sex education" **OR** psychoeducation* **OR** psychosocial

AND

- condom* **OR** contracept* **OR** "birth control" **OR** "barrier method" **OR** "family planning" **OR** abstinen* **OR** "safe sex" **OR** "AIDS prevent*" **OR** "sexually transmitted diseases" **OR** "reproductive health" **OR** "premarital intercourse" **OR** "sexual health

***Search terms and methods of combining them were considered with a senior academic librarian with experience of database searches.**

Appendix B: SR Databases

	Number of References
Medline	2892
CINAHL	1290
Embase	2513
Cochrane	697
PsychInfo	2208
AHMED	19
NICE	0
BNI	34
BioMed	6104
Maternity and Infant Care	203
PUBMED	1025
Science Direct	8
Science Citation Index (Web of Science)	3868
Wiley Interscience (not Cochrane)	654 (only first 500 most relevant were able to be imported)
Experts/organisations*	3
Total	**21364**
Minus duplicates	**11619**

All 11619 reference titles were scanned in the initial elimination process. Titles were scanned according to whether they included some reference to sexual behaviour or drinking behaviour. If they did not the abstracts were scanned for such terms. If they included no mention of either they were deleted.

N.B. Please note, no cut-off date was imposed on the search at this stage of the process, thus entire databases were searched from their initial date of origin to the time of data collection (January 2009).

*Two experts were contacted for key published and unpublished studies in the field (B. Leigh at the University of Washington and R. Cook at the University of Pittsburg). Two sexual health based UK organisation were contacted, the Family Planning Association and the Society for Sexual Health Advisors as well as two UK alcohol organizations (Alcohol Education Research Council and Alcohol Aware).

Appendix C: Data Extraction Form

Paper eligible for inclusion? Yes ☐ **No** ☐

(the paper must satisfy criteria 1-7 to be included in review)

Initials of reviewer **Journal title**

Year of publication **Author/s**

1. Is there a full article to be reviewed in English? Yes ☐ No ☐

2. Was the paper published during or after 2001? Yes ☐ No ☐

3. Does the paper describe a psychosocial-based intervention designed to encourage condom use?
   Yes ☐ No ☐

4. Does the paper involve an intervention conducted in the western developed world (including UK, North America, Europe, Australia, Canada and New Zealand)?
   Yes ☐ No ☐

5. Does the paper describe a study of prospective/longitudinal design (i.e., does the intervention take place over the forward passage of time and include more than one episode of data collection)?
   Yes ☐ No ☐

6. Was condom use reported as an outcome measure? Yes ☐ No ☐

7. Did part or all of the sample use alcohol in excess during the time in which the intervention took place?
   Yes ☐ No ☐

Please complete the following details where possible

I. What was the source of the study population?

II. How long was the period over which the baseline sample was recruited?

III. How was the population sampled?

IV. What was the setting in which the intervention took place?

V. What was the length of follow-up?

VI. How many times was data collected throughout the study (i.e., how many times were outcome measures recorded)?

VII. What was the size of the sample used in analysis and what was the size of the sample at the beginning of the study?

VIII. What were the main results reported (including *p values* and *confidence intervals*)?

IX. Was a power calculation performed, and if so what effect sizes were reported?

X. Was the intervention theory based, and if so by what theory?

XI. Give a brief account of what the intervention entailed (including structure and delivery of intervention)

XII. Was condom use measured at baseline and post-intervention and if so how was this recorded?

XIII. How was excess alcohol use defined and measured?

XIV. Where there any adjustments made for confounding variables?

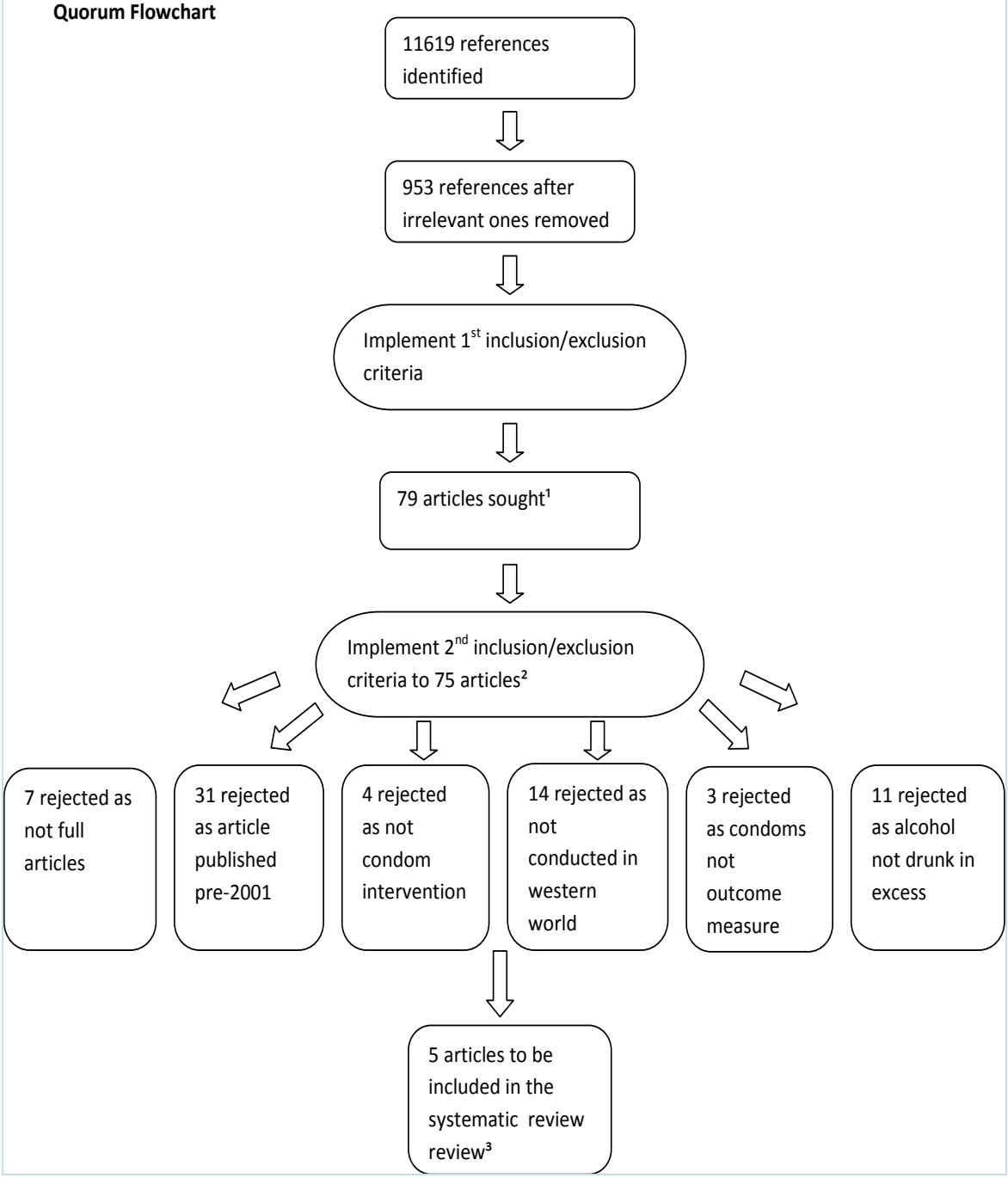
XV. Where there any sources of bias in the execution of the study?

XVI. Are there any other additional comments to note?

XVII. Are there any other potentially useful studies identifiable from the reference lists? Please note author/s, year of publication and journal title.

Appendix D

Quorum Flowchart



1. There were discrepancies between the two markers at this stage. 90 and 77 papers were identified by markers 1 and 2 respectively. These discrepancies were resolved to result in 79 papers being sought as full articles.
2. Three papers were unable to be located (two of which would have been later rejected as too old). One paper also arrived for inclusion too late (this would have been rejected as too old as well).
3. Three out of the five papers were agreed on initially, the rest were resolved between the two markers

Appendix E: Adapted Jadad for Quality Assessment Tool (taken from Jadad *et al.,* 1996)

1. Was the study described as randomised (this includes use of the words such as randomly, random and randomisation)?
2. Was the study described as double blind?
3. Was there a description of withdrawals and dropouts?

Scoring the items:

Either give a score of 1 point for each "yes" or 0 points for each "no". There are no in-between marks.

Give 1 additional point if:	For question 1, the method to generate the sequence of randomisation was described and it was appropriate (table of random numbers, computer generated, etc).
And/or	If for question 2 the method of double-blinding was described and it was appropriate
Deduct 1 point if:	for question 1, the method to generate the sequence of randomisation was described and it was appropriate (patients were allocated alternately, or according to date of birth, hospital number etc).
And/or	For question 2, the study was described as double blind but the method of blinding was inappropriate

Guidelines for Assessment

1. Randomisation – A method to generate the sequence of randomisation will be regarded as appropriate if it allowed each study participant to have the same chance of receiving each intervention and the investigators could not predict which treatment was next. Methods of allocation using date of birth, date of admission, hospital numbers, or alteration should not be regarded as appropriate.
2. Double blinding – A study must be regarded as double blind if the word "double blind is used. The method will be regarded as appropriate if it is stated that neither the

person doing the assessments nor the study participant could identify the intervention being assessed.

3. Withdrawals and dropouts – participants who were included in the study but did not complete the observation period or who were not included in the analysis must be described. The number and the reasons for withdrawal in each group must be stated. If there were no withdrawals, it should be stated in the article. If there is no statement on withdrawals, this item must be given no points.

Appendix F: Adapted Jadad for Quality Assessment Tool (taken from Jadad *et al.,* 1996): Scoring Results

	Randomisation	Double Blind	Withdrawals or Dropouts	Additional Points	Deducted Points	Total Score
Celentano *et al.* (2002)	1	0	1		-1	**1**
Ingersoll *et al.* (2003)	0	0	1			**1**
Jemmott *et al.* (2005)	1	0	1	1		**3**
Dal Cin *et al.* (2006)	1	0	1		-1	**1**
LaBrie *et al.* (2008)	1	0	1		-1	**1**

Part 2: Bridging document – linking the systematic review to the research

The findings of the systematic review conducted by the author in 2008 to 2009 (Part 1 of this thesis) found that there is a lack of good quality interventional research addressing the use of condoms in those that binge-drink. The refinement of the research question through to data collection and analysis occurred during the years 2010 to 2011 with the write-up for this research taking place more recently. During this time there have been changes to government and policy, practice and data pertaining to sexual health and alcohol use. These changes and the impact of them will now be considered as part of the changing context for this piece of research.

At the time of conducting the systematic review, the key governmental paper to refer to regarding sexual health was the National Strategy for Sexual Health and HIV published by the Department of Health (2001). This document set out a ten year strategy aimed at bettering sexual health and sexual health services including reducing the prevalence and transmission of HIV and other STIs as well as reducing unintended pregnancy. This policy, considered alongside the ten year Teenage Pregnancy Strategy launched in 1999 marked a concerted effort to improve sexual health and outcomes, particularly for young people. Indeed, it has been reported that conceptions in 15- to 17-year olds started to decline in 2008 and have continued to do so resulting in the lowest teenage conception rates since records began (Arie, 2014). However, whilst the Framework for Sexual Health Improvement in England (published by the Department of Health, 2013) aimed to continue improving sexual health and reducing unintended pregnancies, the absence of funding for specific strategies addressing teenage conceptions and the lack of policy addressing compulsory sex and relationships education continues (Arie, 2014). There is however a marked difference in the

two documents pertaining to the subject matter of this thesis in that the latter publication considers the role of alcohol use in the sexual context and which possibly reflects the growing body of knowledge around the use of alcohol and it's impact on sexual behaviour.

A decline in teenage conceptions might prompt an expectation of decreased STIs in young people, however Public Health England (2013) report that new STI diagnoses rose by 5% in 2012 with the highest rates of STIs being found in those aged less than 25 years. Whilst advances in screening are considered to account for much of this rise, such figures would suggest that the acquisition of STIs as a result of unsafe sex remains problematic. Decreases in conception rates in some groups considered alongside rising STI rates might be explained by the use of non-barrier methods of contraception which are effective against pregnancy but provide no protection against STIs. Confirming this, a UK study found that provision of emergency hormonal contraception through pharmacy schemes is associated with higher rates of STIs in teenagers (Girma and Paton, 2011). Whilst Goldstein, Upadhyay and Raine (2012) found that when they followed the condom use of women for twelve months after commencing a hormonal contraceptive method, condom use decreased by almost one third from baseline to the end of the follow-up period. In addition, if the hormonal method of contraception was subsequently discontinued around half of the women failed to resume condom use. These findings prompt the authors to suggest that providers promote the use of dual contraceptive methods (i.e. condoms plus one other method). Identifying efficacious health interventions that promote the use of condoms therefore remains a justified focus of research.

The influence of alcohol including binge-drinking behaviour on condom use as well as a risk factor for HIV and STIs has been the subject of an increasing amount of research over recent

years. For example, a recent meta-analysis has found the consumption of alcohol to be associated with HIV infection (Baliunas *et al.*, 2010). Wells *et al.* (2010) found that in their sample of young adults, binge-drinking was reported on 52% of drinking days with the majority reporting recent sex following drinking (62%) with many reporting being less safe than they would have preferred to be owing to alcohol use (29%). Whilst there has been more recent research focusing on reducing alcohol-exposed pregnancies in binge-drinking college students (Ceperich and Ingersoll, 2011) there still appears to be a lack of interventional work focusing on promoting the use of condoms in binge-drinking populations despite the high prevalence of both STIs and binge drinking in young people.

It is therefore hoped that both the systematic review (reported in Part 1 of this thesis) alongside the feasibility study which it helped inform (reported in part 3 of this thesis) goes some way to exploring this apparent gap in the literature and contributes to the much needed body of original literature addressing these important and contemporary issues.

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Part 3: Research study

Evaluation of a skills-based condom intervention in an alcohol-using student population: a feasibility study

Contents

Abstract

Young people are, as a group, at risk of sexually transmitted infections (STIs), unwanted pregnancy and binge-drinking. The primary method of contraception that offers protection against both pregnancy and STI transmission is condoms. Whilst research examining the relationship between alcohol use and sexual behaviour suggests a complex association dependent on many factors, it is vital that interventions devised to encourage condom use are effective in binge-drinking populations. This feasibility study arose from a systematic review of the literature identifying the previous skills-based interventional work of Jemmott *et al.* (2005) as the most robust of its kind in the field. An adapted version of this skills-based intervention was put together using national resources for use with a university binge-drinking population in the UK. This feasibility study identified changes to practical condom skills, theoretical condom knowledge and skills, intentions to use condoms and condom use self-efficacy for the information-only group and skills-based group with tentative findings suggesting an increased retention of knowledge for the skills-based group in terms of theoretical knowledge and skills. Actual condom use was not found to have improved at follow-up 4–7 weeks post-intervention. These findings will be discussed here in terms of what they can tell us about the feasibility of running a powered trial, and a number of recommendations arising from the observed strengths and limitations of the current study and intervention content will be proposed.

1.0 Background

Binge-drinking and sexual health are two issues pertinent to the public health agenda in the UK today, particularly with regards to young people. The following chapters within this Background section seek to define these issues, detail the extent of these problems, understand how they may be related and what the implications of these issues are in terms of health interventions. Their relevance to the undertaking of the current study is also described.

1.1 Binge-drinking

Issues concerning the definition of binge-drinking are now described as well as information regarding the consequences and prevalence with a focus on young populations.

1.1.1 Definitions and possible consequences of binge-drinking

Binge-drinking, referred to as "the consumption of excessive amounts of alcohol within a limited time period" has been identified as a characteristic of the British drinking culture and prevalent among young people (Parliamentary Office of Science and Technology, 2005, page 1). Current guidelines such as that published by the Information Centre for Health and Social Care (2011) state that men should not drink in excess of 3–4 units of alcohol per day and that women should not drink more than 2–3 units per day. Despite these guidelines, however, the British Medical Association (BMA Board of Science, 2008) suggest that there is no standard definition of binge-drinking, although reference is made to the Prime Minister's Strategy

Unit's (2003) classification of a "binge" to be more than twice the daily recommended guidelines. Indeed, this threshold of eight units for men and six for women is often operationalised within the research literature (Cooke, French and Sniehotta, 2010). Ambiguity regarding the definition of binge-drinking also appears within the views of lay populations. For example, Cooke, French and Sniehotta (2010) found that in a study involving undergraduate students, participants generally overestimated how many units constituted binge-drinking. The authors suggest that there is wide variation in how the term "binge-drinking" is understood. In a review of the literature, Murgraff, Parrott and Bennett (1999) cite a more qualitative definition of binge-drinking referred to as "risky single-occasion drinking", or RSOD. This definition encapsulates the element of risk associated with such behaviour with possible consequences reported including crime, car accidents, STIs, HIV and unplanned pregnancies.

1.1.2 Prevalence of binge-drinking

Data supporting the assertion that binge-drinking is prevalent among young people is reported by the Information Centre for Health and Social Care (2011), which suggests that 24% of men and 23% of women aged 16–24 years drank more than the recommended guidelines of eight units for men and six units for women at least one day in the previous week and, in women, those in the 16–24 age group were most likely to drink more than 35 units per week (6%). The Parliamentary Office of Science and Technology (2005) also reported that binge-drinking in young British women had increased more in Britain than in any other EU country

in the previous decade. Young people are therefore a population considered to be at risk of binge-drinking.

1.1.3 Binge-drinking in student populations

Binge-drinking amongst young people has been explored within undergraduate populations in the UK. In a review of the literature considering alcohol use in undergraduate students in the preceding 25 years, Gill (2002) found that as many as one in two male students take part in binge-drinking and that three times as many female students compared to the general population exceed alcohol guidelines. Similar findings have been reported by Cooke, French and Sniehotta (2010) and Norman, Armitage and Quigley (2007), who both report that around 60% of undergraduates binge-drink (in these cases defined as more than seven and 10 units for women and men respectively).

To summarise, binge-drinking is prevalent in young populations such as university students, and the possible negative consequences which have been previously mentioned may include anti-social behaviours and negative health outcomes such as STIs and unplanned pregnancy.

1.2 Sexually transmitted infections (STIs) and unplanned pregnancy

As binge-drinking has been found to be particularly prevalent in young populations and STIs and unplanned pregnancy have been identified as possible consequences, the prevalence and associated health consequences of these will now be considered.

1.2.1 The prevalence of STIs and unplanned pregnancy

Public Health England (2013) report that young people (those under 25 years of age) experience the highest rates of STIs and contributed to the majority of STI diagnoses in heterosexuals in 2012 particularly in terms of genital wart diagnoses and chlamydia diagnoses (54% and 64% respectively). As most people become sexually active in young adulthood, these findings are not so surprising. However, they do highlight the vulnerability of this particular age group. A cross-sectional survey at a UK university found that 22.4% of students had had two or more sexual partners in the previous year with inconsistent condom use. In addition, lifetime prevalence of a sexual infection was cited to be 9.6% (Vivancos, Abubakar and Hunter, 2008), highlighting the vulnerability of student populations to STIs. Likewise, although most recent data from the Office for National Statistics (2013) suggests that the number of under-18 conceptions in England and Wales is the lowest since records began, the UK is still considered to have one of the highest birth rates in the European Union.

1.2.2 Possible consequences of STIs and unplanned pregnancy

There are many potentially adverse effects of contracting an STI. For example, some STIs can increase the acquisition of HIV, STIs such as chlamydia and gonorrhoea can cause pelvic inflammatory disease (PID), which can lead to infertility, and some STIs can lead to cancer, such as human papillomavirus (HPV) infection (World Health Organization, 2013). Having children at a young age is associated with poorer outcomes, both socially and in terms of well-being for both mother and child (Department for Education and Skills, 2006).

To summarise, poor sexual health such as STIs and unplanned pregnancy can have adverse health and social consequences. Indeed, the recent publication of *A Framework for Sexual Health Improvement in England* (Department of Health, 2013) suggests that reducing STIs and unwanted pregnancies remains a priority area and that the use of preventative evidence-based interventions is supported to improve these outcomes.

1.3 The relationship between binge-drinking and STIs

The evidence would therefore suggest that young people are a group at risk of binge-drinking and poor sexual health, which can lead to negative outcomes. The relationship between alcohol use and sexual risk-taking will now be considered as well as theories suggesting potential mechanisms that may underpin these relationships, such as alcohol-sex expectancies and alcohol myopia theory.

1.3.1 A relationship of general association

A UK study matching genitourinary clinic attendees with a matched cohort from the General Household Survey (GHS) found that the GHS cohort reported a median value of six units of alcohol to constitute a "usual" drinking night, whereas the clinic cohort reported a median value of 13.4 units (Standerwick *et al.*, 2007). Likewise, 86% of the clinic cohort were found to exceed UK Government binge-drinking thresholds compared to 54% of the GHS cohort, leading the authors to suggest that "the majority of typical STI clinic attendees in this study are very heavy binge drinkers" (p. 812). Of those women attending clinic, it was found that

76% reported having unprotected sex as a result of drinking. Such data supports a strong association between alcohol use and risky sexual behaviour, although, conversely, research conducted by Parks *et al.* (2011) explored condom use among female bar drinkers and found no temporal association between condom and alcohol use and suggest that situational, individual and contextual factors are important when considering the effects of alcohol use on whether sex is protected by the use of condoms.

1.3.2 A relationship of causality

On a global level, alcohol use at sexual debut in particular is one of the key patterns of behaviour that has been identified from large, cross-cultural studies exploring the interaction between alcohol use and sexual behaviour (World Health Organization, 2005). This raises an interesting question in terms of whether people drink alcohol in order to facilitate sex or have sex as a result of drinking alcohol. A systematic review of the literature carried out by Cook and Clark (2005) found support for an association between STIs and problematic alcohol use, although the authors note that no causal relationship could be ascertained. The authors note that alcohol may lead to increases in STI rates by exerting its effects on behaviour, sexual arousal, by compromising the immune system or as a confounder variable such as a personality trait, for example sensation-seeking. The effects of sensation-seeking and unsafe sex are explored by Donohew *et al.* (2000). They found that in American high school students both impulsive decision-making and sensation-seeking were strongly related to sexual risk-taking. In a meta-analysis, Leigh (2002) also recognises the potential for confounding variables in research exploring the link between alcohol and unsafe sex and,

whilst event-level methodology is proposed as the preferred approach, Leigh (2002) acknowledges its limitations in eliminating confounders.

1.3.3 The role of alcohol-sex expectancies

An alternative approach to the relationship between alcohol and sexual behaviour is to consider the role of alcohol expectancies. Alcohol expectancies are defined by LaBrie *et al.* (2005) as "beliefs and ideas about the positive and negative effects that alcohol has on an individual's behavior" (p. 260), with a further definition for sex-related alcohol expectancies to cover beliefs pertaining to the role of alcohol in sexual disinhibition, condom use and sexual arousal, for example. The role of alcohol-sex expectancies in the decision to use condoms has been researched. Walsh *et al.* (2011) report college women used condoms less frequently if they had strong negative alcohol-sex expectancies, i.e. a greater belief that alcohol use would lead to decreased use of condoms. They also found that condom use declined over the first year of college in women that binge-drank. This finding is supported by previous research, such as that conducted by Corbin and Fromme (2002), who found alcohol-sex expectancies to be associated with decreased condom use at first intercourse with an overall greater effect being observed early on in relationships.

1.3.4 Alcohol myopia

Explanations for decreased condom-use whilst intoxicated with alcohol have been put forward which consider the role of alcohol myopia theory which has been investigated by

MacDonald *et al.* (2000). They found that when young men were intoxicated they were more likely to possess favourable attitudes to sex without a condom when aroused compared to their sober counterparts. MacDonald *et al.* (2000) suggest that this is due to alcohol reducing cognitive capacity so that only the most salient of cues are attended to; in this case, the negative consequences of unprotected sex are over-ridden by the perceived benefits of sex without a condom. However, in a previous study MacDonald, Zanna and Fong (1996) did not find a similar effect for alcohol in women, which was explained in terms of the fear of pregnancy being a more salient, inhibiting cue. These findings highlight the complexities in predicting safe sex behaviours.

1.3.5 Predicting condom use

Meta-analysis of condom use in heterosexual populations suggests that holding beliefs and possessing knowledge about the threat of STIs and HIV infection are not enough to ensure condom use (Sheeran, Abraham and Orbell, 1999). A social psychological approach to conceptualising condom use is instead proposed with particular support being found for an extended Theory of Reasoned Action (TRA) model. In terms of considering condom use when alcohol is used, Bryan *et al.* (2005) found that alcohol use did not alter attitudes to condoms, intentions or behaviour. When considering constructs of the TRA and Theory of Planned Behaviour (TPB), intentions were found to be a significant predictor of behaviour.

In summary, it would seem that there are myriad problems for research in the field of sexual behaviour and alcohol use. The relationship between alcohol and safe-sex behaviours such as condom use is not as straightforward as conventional wisdom would often suggest. As

Standerwick *et al.* (2007) make reference to in their study, there are difficulties ascertaining to what extent alcohol may increase one's chances of developing an STI in the absence of data for those drinkers who have unprotected sex and do not develop an STI. In addition, most research is unable to draw causal inferences, owing to cross-sectional or retrospective study designs and because, by its very nature, self-reported data concerning alcohol and sexual behaviour is apt to be distorted as a result of memory or demand effects. However, despite these complexities, with young people being at risk of both binge-drinking and poor sexual health, it is important that interventions designed to reduce unsafe sex are effective for those who use alcohol.

1.4 Safe-sex interventions

As using condoms consistently and correctly at every episode of sexual intercourse has been found to be an important strategy in reducing the transmission of STIs and HIV (Alfonsi and Shlay, 2005), many interventions have attempted to promote their use. The effectiveness of such interventions, their theoretical underpinning and characteristics are now considered. A discussion of gender specific issues in condom negotiation also follows.

1.4.1 Intervention effectiveness

Robin *et al.* (2004) reviewed a decade of behavioural interventions designed to reduce STIs and pregnancy in adolescents. In assessing effectiveness, they found the most consistent positive impact for interventions that targeted condom use (as opposed to delaying sexual

intercourse) as well as other factors such as adequately trained facilitators, satisfactory duration and intensity of interventions. These findings are supported by a review of reviews exploring sexual risk-taking in young people (Jepson *et al.*, 2006) which found that interventions to increase the uptake of contraception as opposed to promoting abstinence were more successful and that interventions were more effective if they targeted the promotion of condom use as opposed to attempting to decrease numbers of partners or frequency of sex.

1.4.2 Theoretical underpinning of interventions

Ellis and Grey (2004) report that there is "sufficient review-level evidence" to suggest that interventions are more likely to be effective if they are developed with theoretical models in mind. The theoretical underpinning of the safe-sex interventions reported here is varied. Robin *et al.* (2004) report that the most commonly utilised models and theories in their review included Social Cognitive Theory, Social Learning Theory, the Health Belief Model and Social Influence Theory with many interventions being based upon a combination of theories. Shepherd *et al.* (1999) report that with the exception of one, all of the included studies in their review were theoretically underpinned with the most frequently cited theory being Social Learning Theory which later became known as Social Cognitive Theory (Bandura, 1986). Central tenets of these theories such as self-efficacy, modelling and vicarious learning often feature within condom interventions in the form of generic skills-building, specific practical condom use skills and safe-sex negotiation skills via observation of others, role-playing and practical exercises (Robin *et al.*, 2004 and Shepherd *et al.,* 1999). The

incorporation of practical, skills-based techniques leading to an improved acquisition and retention of knowledge also fits with early approaches to learning, such as those put forward by Gibbs (1988) and Kolb (1984), which suggest that learning by doing (experiential learning) leads to more sustained success when trying to master new skills.

As Bandura (2004) suggests, "beliefs in personal efficacy play a central role in personal change" (p. 144). Thus in the case of condom use, this common-sense approach would suggest that one needs to perceive one has the self-efficacy to correctly use condoms in order for this behaviour to be adopted and maintained. The role of self-efficacy is central to the Health Action Process Approach (HAPA) developed by Schwarzer (1992) which includes a motivational and volitional stage, the former involving evaluations of self-efficacy and the latter involving the formation of action plans. As Ogden (2004) suggests the inclusion of habit and time render this model particularly relevant when considering condom use and indeed, Teng and Mak (2011) report the HAPA can be successfully applied to the decision to use condoms and suggest that health promotion efforts focus on boosting self-efficacy and planning.

Despite varied models and theories underpinning sexual health interventions, Jepson *et al.* (2006) report that they identified no systematic reviews evaluating the effectiveness of such models. They suggest there is a lack of evidence to identify any particular models or approaches which are effective in changing attitudes, knowledge or behaviour and it is therefore not possible to draw conclusions as to what approaches are most effective. Indeed the many complex determinants of condom use may favour a combination of models or extended versions on which to base interventions such as that conducted by van der Velde and van der Pligt (1991) who extended the Protection Motivation Theory (PMT) to include

additional variables such as previous behaviour, social norms and coping styles (and thus increasing explained variance to 73% in heterosexual participants). Alternatively, condom interventions based upon one particular model have had previous reported success when focussing on one discrete element of condom use such as carrying a condom as reported by Armitage and Talibudeen (2010) who based their intervention upon the TPB.

1.4.3 Intervention characteristics

Ellis and Grey (2004) report that there is "sufficient review-level evidence" to suggest that interventions delivered in small groups can be effective and that they are more likely to be effective if they include behavioural skills training and are targeted in terms of gender and culture. Indeed, a review by Shepherd *et al.* (1999) found that information-based educational interventions which were complemented by sexual negotiation skills for socially and economically disadvantaged women encouraged behavioural sexual risk reduction. The interventions included in this latter review included those designed to promote condom use, refusing sex without a condom, teaching condom use on anatomical models and safe-sex negotiation. The included interventions were considered in terms of outcomes such as condom use, attitudes, knowledge and self-efficacy. Shepherd *et al*. (1999) suggest that multifaceted content is required to reduce sexual risk behaviour characterised by a combination of information provision with more practical facets in motivation, skills and attitude change. They also suggest that the most favourable mode of delivery appears to be small group-led sessions including discussions and a variety of media.

1.4.4 Gender specific issues in condom use

The literature suggests that many interventions are aimed either at males or at females and that they often have a different focus. For example, negotiation and assertiveness seem particularly important in women's decision to use condoms. For example, De Graaf *et al.* (1997) found that a sex workers' refusal to have unprotected sex was an important factor in a client's decision to use condoms, leading the authors to suggest that sex workers should receive support in their decisions to use condoms. Likewise, Stoner *et al.* (2008) found that women within an experimental situation who were less assertive were less likely to insist on using condoms, prompting the authors to suggest that interventions focus on "sexual assertiveness training to enhance condom insistence" (p. 1167). Indeed, the Theory of Gender and Power (Wingood and DiClemente, 2000) encapsulates the difficulties women may face negotiating safe-sex strategies in relationships and would suggest that issues of assertiveness and self-efficacy are particularly pertinent in female groups when considering condom use. This is also supported by Boer and Mashamba (2007) who found that whilst self-efficacy was an important factor in condom intentions for women, subjective norms were a more salient factor in men.

It would therefore seem that there is review-level evidence to suggest that interventions designed to promote condom use can be effective, particularly if theoretically underpinned, targeted in terms of gender and culture and if incorporating some form of skills or behavioural training. However, in the absence of any review focusing on whether condom interventions were effective specifically in binge-drinking populations a systematic review was carried out by the author, a discussion of which now follows.

1.5 Rationale for systematic review

Up until 2008, no systematic reviews of the literature had been carried out exploring whether interventions designed to promote condom use were effective in binge-drinking populations. The author therefore set about conducting such a systematic review which is reported in Part 1 of this thesis.

1.5.1 Findings emerging from the systematic review

A total of five articles were included in the review and subject to narrative synthesis. Although most studies suggested that the interventions were effective in encouraging condom use in those who drink excessively, internal and external validity was not good across most studies. Many conceptual difficulties in establishing binge-drinking behaviour as well as methodological difficulties in the execution of the research and study design were identified. Some interesting findings emerged from this review which pointed to future avenues of exploration, including applying the skills-based approach adopted by Jemmott *et al.* (2005) (clearly identified as the most robust study included in the review) to a specific binge-drinking population. The systematic review concluded that, although there is evidence to suggest that interventions can be effective in encouraging condom use in binge-drinking populations, further research is required to address the methodological limitations described. These include robust study designs, including a true control group and baseline measures, incorporating data which does not rely solely on self-report, clearly defining binge-drinking populations and considering condom use while intoxicated.

The systematic review therefore identified a clear need for further research in this area as well as future avenues of exploration. This formed the basis of the current feasibility study. The current research therefore is a clear and logical progression of this systematic review.

1.6 Research rationale

The evidence contained in this Background section suggests that young people are a population at risk of both binge-drinking and STIs and unplanned pregnancy. Whilst there is sufficient review-level evidence to suggest that interventions designed to encourage condom use can be effective, the lack of review-level evidence exploring whether interventions designed to encourage condom use are effective in binge-drinking populations prompted the author to conduct a systematic review to address this gap in the literature. This systematic review revealed that, whilst a number of interventions had been conducted to increase condom use in those who use alcohol, a number of methodological issues were identified. A number of recommendations for future research were identified from this systematic review, including the proposal of running the skills-based intervention adopted by Jemmott *et al.* (2005), which clearly emerged as the most robust study within this review within a defined, local binge-drinking population.

1.6.1 Research aims and objectives

The aim of this research was to conduct a feasibility study to determine whether a culturally specific version of a study based on the skills-based intervention formerly devised by

Jemmott *et al.* (2005) in a UK university binge-drinking population could be rolled out across a wider population.

The research objectives of this study are:

1. To determine whether the Jemmott *et al.* (2005) study could be adapted using available UK materials and a compatible intervention programme devised for use in a UK university-based binge-drinking population.

2. To conduct a feasibility study of the UK-adapted version of the Jemmott *et al.* (2005) intervention programme aimed at improving condom use in a UK university-based binge-drinking population.

3. To appraise the efficacy of running the UK-adapted version of the Jemmott *et al.* (2005) intervention programme considering issues such as recruitment, data collection, delivery of the intervention, content and appropriate analysis of findings.

To summarise, this research seeks to contribute to the body of literature exploring condom use in young people who binge-drink, which is identified as an area of priority in young people's health. This will be done by running a skills-based condom intervention based on Jemmott *et al.* (2005) in a specified binge-drinking, university population whilst addressing the methodological limitations of previous research as identified by the systematic review reported in Part 1 of this thesis and page 72 of this Background section.

2.0 Method

The critique of methodology found in research identified by the systematic review reported in Part 1 was used to inform the methodology of the current research. The following chapters within this Method section detail how some of the limitations of this previous research were addressed particularly in terms of study design, sample and measures.

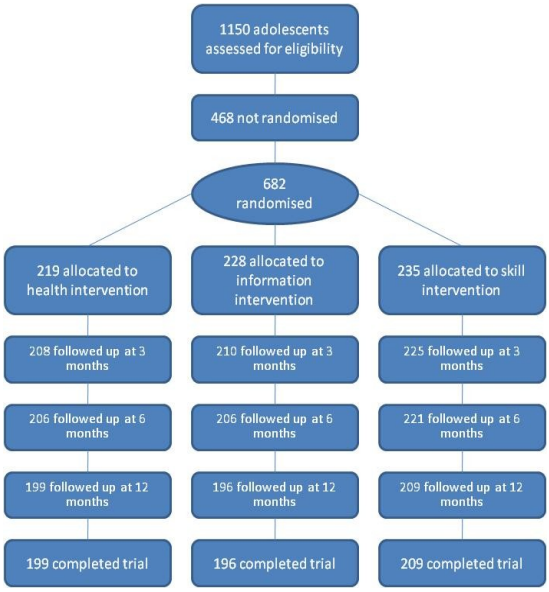
2.1 Design

In order to address some of the research limitations highlighted by the systematic review reported in Part 1, such as a lack of a true control group and of adequate baseline measures, this study was based on a three-arm design (information-only group, skills-based group and control group) with data collected at three time-points (baseline, post-intervention and follow-up). Indeed, the Medical Research Council (2000) acknowledge that a randomised controlled trial (RCT) provides an optimal framework for reducing opportunities for bias, and whilst a three-arm design was opted for in this instance it was not possible to engineer true randomisation (identified as the most robust means of minimising selection bias by the Medical Research Council, 2008) or double-blinding in the current study due to the nature of recruitment and opportunities for assigning facilitators/assistants to intervention sessions (discussed in due course). The maximum follow-up period was utilised in order to observe changes in behaviour over time. This was dictated by the submission of research credits and amounted to 4–7 weeks dependant on the date of the initial intervention session.

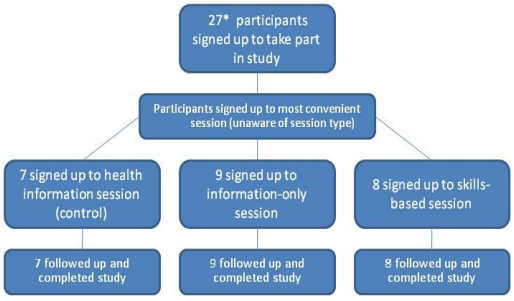
This study can therefore be described as a prospective, non-randomised, controlled trial in that the intervention conditions were manipulated by the author under controlled conditions

and that intervention assignment was concealed from the participants upon study entry (Bowling, 2005). A diagram detailing the design of the current study in comparison to the Jemmott *et al.* (2005) study can be observed below (Diagram 2.1). A GANTT chart showing the timeframes of the key study milestones can be viewed in Appendix 1.

Diagram 2.1: Comparison of study design between Jemmott *et al.* (2005) and current study



I: Original study: diagram obtained from Jemmott *et al.* (2005)



II: Current study (*3 participants took part in Void Control)

2.2 Cultural specificity

As the intervention content tested by Jemmott *et al.* (2005) was intended for a different population in terms of culture and age, it is necessary to consider the appropriateness of the intervention content for the target population in this study. These requirements forming the basis of the current feasibility study will now be considered.

2.2.1 Rationale for feasibility trial and content adaptation

The Medical Research Council (2008) suggest that sufficient piloting and feasibility work be carried out prior to a main evaluation study in order for accurate assumptions to be made regarding recruitment and retention of participants as well as acceptability and delivery of the intervention. Indeed, the rationale for the current feasibility study is to identify these parameters in order to inform a larger-scale study.

The World Health Organization suggests that interventions in the area of alcohol and sexual behaviour be "culture-specific" (World Health Organization, 2005). The original intervention conducted by Jemmott *et al.* (2005) and ran in the United States was "designed to be culturally and developmentally appropriate for inner-city African American and Latino adolescent girls" (in the 12- to 19-year-old age range) and targeted "the elevated risk of HIV and STD among inner-city African American and Latino young women" (p. 441). The content for this study therefore needed to be adapted for a UK university, binge-drinking audience, recreating the intervention content like for like as far as practicably possible whilst being culturally and developmentally appropriate. For example, the focus on sexual health would be more appropriately geared towards STIs as opposed to HIV as these are more prevalent in young people in the UK (Public Health England, 2013). The current intervention content therefore strived to reflect the relevant cultural context (in terms of demographics and in keeping with the focus on alcohol) in relation to the target population and appropriate materials were sourced to support this. For example, all Internet clips that were shown were derived from NHS sources (as opposed to the US materials used in Jemmott *et al.*) and centred on sexual health issues in young people. Exercises from national organisations and charities such as Brook, DrinkAware and 4Thought Solutions were included because of their

age and cultural relevance, for example whilst Jemmott *et al.* (2005) incorporated an AIDS basketball game into their culturally relevant intervention content an adapted "spin-the-bottle" game was incorporated into the current content, thus providing a more relevant activity intended for an undergraduate population. Content was also obtained from Avert and the International Planned Parenthood Federation (IPPF) and was opted for owing to its focus and appropriateness.

2.3 Intervention content

In order to minimise design bias in the form of unequal intervention conditions, each research condition was designed to be equitable in length and in terms of participant enjoyment whilst making use of a similar range of media (flip-chart exercises, Internet clips, anatomical model demonstrations and group discussion). The aim of the information-only condition was to assess the impact of receiving information about condom use and safe sex without the opportunity to practise condom skills or negotiation. This was to provide a point of comparison with the skills-based condition which forms the content under investigation (the opportunity to practise condom skills and negotiation in combination with information about safe sex and condom use). The control group provided a blank arm to this controlled trial. A description of how the content was developed, the differences between conditions and a consideration of equipoise now follows.

2.3.1 Content development

The content devised by Jemmott *et al.* (2005) was based on "cognitive behavioural theories" (p. 441) and included elements such as beliefs about condoms and risk reduction, personal vulnerability to STIs and HIV, barriers to condom use as well as depicting effective condom use and negotiation skills. A skeleton schedule was sought from Jemmott *et al.* (2005) detailing the basic modular format with which to guide the current intervention content (this can be viewed in Appendix 2). A more detailed curriculum was available at a price not within the means of the author. Guidelines published by the National Institute for Health and Care Excellence (NICE, 2007) suggest that whilst the evidence does not support any one particular model of behaviour change there are a number of concepts which can be incorporated in to health promoting interventions including personal relevance, outcome expectancies, self-efficacy and subjective norms. The content forming the basis of the current intervention (see Appendix 3a) was therefore devised with these concepts and those pertaining to cognitive behavioural theories such as Social Cognitive Theory (Bandura, 1986) in mind. Sources were contacted requesting resources such as games ideas, leaflets, condoms and anatomical models, exercises to promote discussion and National Health Service Internet clips (NHS, 2010) to include in this feasibility study that would be culturally and age-appropriate to the target population. A list of all sources contacted and the resources which were utilised can be viewed in Table 2.1. An inventory of equipment and resources used according to intervention session can be viewed in Appendix 4. The modular intervention content forming the basis of the current intervention addressing knowledge, personal vulnerability, skills and negotiation/role play is described below with consideration as to how the component parts link to psychological concepts and theory.

Table 2.1: Sources contacted and resources used

Service Provider/Organisation	Outcome	Resources Used
Jemmott/Select Media	Skeleton intervention format	☑
NHS Choices (www.nhs.uk)	Video clips	☑
AVERT (www.avert.org)	Quizzes	☑
GHNHSFT Sexual Health Clinic	Anatomical models, condoms, lubricant, Mates condom leaflets	☑
Project 28	Drinkaware resources	☑
Brook	Game and booklets/web resource	☒Board game ☑Booklets/web
Terence Higgins Trust	Leaflets, directed to GMFA	☒
Family Planning Association	Directed to publications list	☒
Society of Sexual Health Advisers	Directed to Sheffield PCT	
IPPF	Directed to www.ippf.org, negotiation materials located	☑
UWE Health Centre	No reply	
DoH Contacts	Directed to FPA, Brook, Sheffield PCT, 4Thought Solutions	
Sheffield PCT	Leaflets/postcards	☒
GMFA	Condom demonstration format	☒
4Thought Solutions	Group exercises	☑

2.3.2 Information-only condition

Knowledge Module: A range of NHS Internet videos were played to the group initially, covering information on HIV and STIs. This provided general sexual health knowledge on which the intervention could be based and introduced the concept of good sexual health as a valued outcome consistent with Social Cognitive Theory (Bandura, 1986). This was then followed by an informal "twenty questions" style quiz (AVERT, 2010) covering myths and facts in sexual health and thereby addressing some of the commonly held misconceptions concerning sexual health. Participants called out the answers to these questions in the group setting to promote discussion and set the scene for the development of positive subjective norms within the group setting which runs through each of the modules of the group programme (consistent with guidelines published by NICE, 2007).

Vulnerability Module: A flip-chart exercise named "What is sexual health?" followed (4Thought Solutions, 2010 – see appendix 3b). This introduced the concept that sexual health is a part of our everyday lives and well-being as opposed to a separate entity and further strengthened the positive outcome of good sexual health introduced in the preceding module. This exercise was also used to generate group discussions about what constitutes various types of health and introduced the concept of personal vulnerability and relevance in relation to sexual health consistent with NICE (2007) guidelines. This was followed by an NHS Internet clip continuing this theme and some slides of STI rates across different age groups which again highlighted personal relevance. An adapted game of "spin the bottle" then followed (obtained from Drinkaware, 2010). This was designed to encourage participants to consider the role of alcohol in various sexual scenarios and as a barrier to using condoms. Some more slides followed containing information about the effects of alcohol on the body (obtained from Brook, 2010) and a last slide focusing on who we may be sexually connected to.

Condom Skills: This module commenced with an NHS Internet clip about the benefits of condom use and was followed by some excerpts from an NHS website regarding common cited reasons for not using condoms. A condom demonstration using an anatomical model and led by the author aided by an assistant focused on how to put on and remove a condom safely and correctly. A range of products were shown and the benefits of their use were discussed with the group (covering male and female condoms, lubricants and dental dams). Participants were not given the opportunity to touch or handle these products. In order to introduce a cognitive-behavioural approach to the session consistent with the format adopted by Jemmott *et al.* (2005), a flip-chart exercise then considered barriers to using

condoms utilising a thoughts/feelings/behaviour and physical sensations model facilitated by the author. Promoting the use of condoms and teaching participants the necessary skills to use them correctly introduced the concepts of outcome and self-efficacy expectancies (consistent with NICE, 2007 guidelines) and was aided by the facilitator-led condom demonstrations based upon modelling and vicarious learning approaches inherent in Social Cognitive Theory (Bandura, 1986).

Negotiation/Role Play: To introduce how to broach the subject of condom use with a partner, an NHS Internet clip depicting condom negotiation was shown. This was then followed by the author and assistant demonstrating common reasons for not using condoms and what one could say in response to these, thereby continuing the theme of modelling and vicarious learning. A range of scenarios were described, with the author and assistant demonstrating through the use of role play (using scenarios obtained from IPPF, 2010) how one could approach condom use with a reluctant partner. Again, participants did not have the chance to practise these role-play scenarios themselves.

2.3.3 Skills-based condition

The skills-based condition followed the same format as the information-only condition, the only difference being that in the skills-based group participants were given the opportunity to handle condoms and practise using condoms in pairs on anatomical models as well as practising negotiation skills through taking part in role play with a fellow participant as opposed to only observing the condom demonstrations and role-play scenarios carried out by the facilitator and assistant as in the information-only group. These additional elements

were included to further strengthen outcome and self-efficacy expectancies regarding condom use via the rehearsal of condom use skills and negotiation skills.

2.3.4 Control condition

This session covered coronary heart disease (CHD), thus providing a blank arm to the controlled trial. A similar format was followed: a range of NHS clips were shown, anatomical models of the heart, arteries and stents were used for demonstration purposes, an adapted "spin the bottle" game for CHD as well as group discussion. Thus, the knowledge and vulnerability modules were akin to those covered in the preceding conditions. The relationship between women and CHD was discussed and a relevant Internet clip was shown in order to highlight personal vulnerability to CHD. The skills and negotiation/role-play modules deviated from the format seen in the alternative conditions but great care was taken to make sure this particular arm of the research was equitable in length and enjoyment to the others.

2.3.5 Void control group

The term "void control" has been used to describe one of the session groups (see Diagram 2.1 and Table 2.2) and appears throughout this thesis. It was named so as it was intended to be the control group although the data provided by it has subsequently been voided and only included in selected analyses. This is because the session was run despite containing fewer participants which then led to a substantially shorter session duration compared to the other

groups (2.5 hours versus 3.5 hours) and thereby producing data not considered to be equitable to the other groups. A subsequent true control group was therefore scheduled with which to provide a more meaningful point of comparison to the skills-based and information-only intervention conditions. Where it has been deemed appropriate and useful, data from the void control group has been included in selected analyses such as in the formation of descriptive data but does not figure in the main analyses pertaining to outcome evaluation.

Table 2.2: Number of participants according to session type

Session type	Date of session	No. of participants per group
*Rehearsal session:	19/11/2010	4
Information-only group:	26/01/2011	9
Skills-based group:	11/02/2011	8
Control group:	16/02/2011	7
**Void control group:	21/01/2011	3
**Data collected from the rehearsal session was used to inform the wider intervention but was not included in the final analyses.* ***The length of the void control group (n = 3) fell short in comparison to the other groups and could not be accurately matched. Data from this group was included in selected analyses to provide a point of comparison against the other groups.*		

2.3.6 Equipoise

In a recent report, Petticrew *et al.* (2013) cite previous assertions suggesting that randomised controlled trials (RCTs) represent the "gold standard" (p.1) in terms of evaluating interventions and that just as equipoise is considered in clinical trials the same should apply to social interventions in that equipoise is a requirement of any RCT. In terms of the current study, whilst Jemmott *et al.* (2005) report robust evidence to suggest that a skills-based intervention was effective in their given population the same cannot be assumed within the

target population of the current study and therefore the assumptions of equipoise can be considered to be met.

2.4 Rehearsal session: Piloting the content

In order to make the intervention content developmentally and culturally appropriate to the participants, a rehearsal session was conducted in the first instance to test the acceptability of the questionnaires (the nature of which pertained to potentially sensitive issues around alcohol use and sexual behaviour), a practical condom exercise and the experimental intervention content. Eight participants were recruited for the rehearsal session, although only four attended. The eligibility criteria to take part in the rehearsal session were the same as for the research sessions. The rehearsal session was delivered jointly between the author and an employee of a local young persons' service (who would later serve as the research intervention facilitator for the skills-based group) who specialised in alcohol and sexual advice. An additional assistant scored the practical condom exercise. The rehearsal session lasted approximately 2.5 hours. Participants were also required to return a follow-up questionnaire, for which 0.5 hours was allocated. Participants gained three research credits for taking part in the rehearsal session, for a total of three hours' research participation. The rehearsal session provided an opportunity for the questionnaire and intervention content to be trialled for acceptability with individuals akin to the proposed research sample in addition to providing a useful rehearsal for the facilitators and assistant. This was particularly important for the condom practical test and associated scoring. Following the completion of the rehearsal session, both the research intervention facilitator and condom practical scoring

assistant were debriefed by the author and minor amendments were made to procedure and the wording of instructions. The rehearsal session also provided useful guidance on how to run the intervention proper, considering such issues as timing and delivery as well as reassurance that the subject matter under investigation was acceptable to this population group. The compiled feedback regarding the questionnaires, practical condom exercise and intervention content is reported in Appendix 5.

2.5 Sample

The following chapter details the rationale behind the chosen sample, the sampling method employed, the eligibility criteria for taking part in the study and the characteristics of the research participants. A prospective sample-size calculation for a full-scale trial is also considered.

2.5.1 Sample rationale

As student populations are at risk of both STIs and binge-drinking (as discussed in chapters 1.1 and 1.2), a university demographic was identified as a key population that may benefit from this intervention. As this intervention primarily sought to enhance negotiation and assertiveness skills, participation was limited to females only. This is consistent with previous research that has highlighted issues around assertiveness and self-efficacy to be more important for women than men in the decision to use condoms (Wingood and DiClemente, 2000; Boer and Mashamba, 2007). Whilst this decision is also consistent with Jemmott *et al.*

(2005), the arising implications in terms of generalisability will be considered in the Discussion and Recommendations section.

2.5.2 Sampling method

Participants were recruited via the participant pool system at the University of the West of England (UWE). This online facility lists various psychology research projects in need of participants and is accessed by first and second-year psychology undergraduates, who are required to fulfil a specified quota of research participation in order to gain research credits. One research credit is generally awarded for one hour of research participation and students are usually required to be awarded 6–8 research credits per academic year dependent on year of study. Research credits are required to be submitted around March/April.

Efforts were made to schedule sessions when the majority of students were not required to attend lectures. This method of recruitment meant that true randomisation was not possible: participants signed up to whatever group session was the most convenient for them. As this was a feasibility study, a total of eight participants per session was aimed for as this was considered the most pragmatic use of the time and resources available. This is also consistent with the literature, which suggests that interventions delivered in small groups can be effective (Ellis and Grey, 2004). Despite advertising the research sessions to require 12 participants (to account for potential non-attendance, as seen with the rehearsal session), a similar number of participants signed up for each research session and there were no non-attendees. Table 2.2 gives a breakdown of participants according to session type and the dates that the sessions took place.

2.5.3 Inclusion/exclusion criteria

Recruitment was limited to females who self-identified as sexually active with males as this was necessary in terms of seeing any potential change in male condom use behaviour. Likewise, it was also considered appropriate to exclude pregnant participants because of issues around condom and alcohol use. In line with recommendations arising from the systematic review undertaken by the author, in order to explore the effectiveness of condom interventions in those who binge-drink, it was decided that in order to be eligible to take part participants must self-identify as drinking six or more units of alcohol on one occasion once a month or more – a threshold used to define binge-drinking in this instance. Based on earlier work conducted by Canagasaby and Vinson (2005), the Screening and Intervention Programme for Sensible Drinking (SIPS) developed the Modified-Single Alcohol Screening Question (M-SASQ) as a brief identification tool for hazardous drinking (Alcohol Learning Centre, 2012). The single item asks recipients, "How often have you had 6 or more units if female, or 8 or more if male, on a single occasion in the last year?" Answers range from "never" to "daily or almost daily" – an answer of "monthly" or more often denotes a positive screen. The M-SASQ is based on one of the original items from the AUDIT developed by the World Health Organization (Babor *et al.,* 2001) and forms the basis of one of the eligibility criteria employed here. Initially, participants were also required not to be taking contraceptives such as the pill, implant or injection. However, this hindered recruitment significantly and so was subsequently omitted.

The eligibility criteria for taking part in both the rehearsal and research sessions therefore required that participants be female, 18–21 years old, not pregnant, sexually active with

males and self-identified as drinking six or more units of alcohol on one occasion once a month or more.

2.5.4 Sample characteristics

Thirty-one females took part in this study. Four took part in the rehearsal session, nine in the information-only condition, eight in the skills-based condition and seven in the control condition. A further three took part in the void control group. All participants were female psychology students at UWE in the first or second year of undergraduate study. Their ages ranged from 18.5 years to 21.5 years at the time of session participation.

2.5.5 Sample-size calculations

As this was a feasibility study, no formal prospective sample size calculations were carried out. Rather, it was deemed appropriate to aim for eight participants per intervention condition as this represented a pragmatic number for the activities to be covered in relation to the availability of resources. This research cannot therefore be considered to have appropriate power to substantiate any hypothesis. Potential sample size calculations if running a full-scale study will be considered in due course.

To summarise, this feasibility study was conducted in a female university population as this group represents a key demographic identified as potentially benefiting from such an intervention. To address some of the methodological difficulties raised by the systematic review in terms of identifying binge-drinkers, the M-SASQ item was applied as one of the

eligibility criteria to ensure participants met a recognised level of binge-drinking behaviour. There were 24 participants as this represented the maximum number of participants per session in terms of the resources available.

2.6 Measures

This chapter describes the procedure for administering questionnaires and the rationale behind the inclusion of each measure incorporated, as well as their reported reliability.

2.6.1 Questionnaire administration

Questionnaires were administered at three time-points: immediately prior to and following the intervention session and at follow-up. The questionnaire administered immediately after the intervention also included a session evaluation form in order to provide a basis for comparing overall participant enjoyment and satisfaction with the session. Follow-up questionnaires were sent out allowing participants approximately one week to complete. The follow-up period varied (from four to seven weeks) depending on the research session date (Table 2.2). Appendix 6 contains an example of Questionnaire 1 (administered immediately prior to the intervention) and Appendix 7 contains the session evaluation form.

2.6.2 Practical condom test

Participants completed a practical condom test (the Measure of Observed Condom Use Skills, or MOCUS) individually before completing the battery of measures in the questionnaire pack. This was considered an important addition to previous research exploring the effectiveness of skills-based approaches, such as those discussed in the systematic review, as assessing improvements to condom skills is fundamental in assessing the effectiveness of skills-based condom interventions. The MOCUS, developed by Lindemann and Brigham (2003), assesses participants on several stages of condom application and removal. This was done immediately prior to and following the intervention session for all conditions. This measure was developed using male and female undergraduate students, and reproducibility has been previously reported to be 0.93 (Lindemann and Brigham, 2003). This practical test was overseen by the same assistant who scored performance according to MOCUS criteria for all participants across all conditions in a separate room in order to maintain consistency. The addition of this measure also provides an alternative to a sole reliance on self-reported data.

2.6.3 Free-standing items pertaining to sexual behaviour

The initial part of the pre-intervention and follow-up questionnaires included free-standing items to measure age (month/year), relationship status, number of episodes of sexual intercourse in previous three months, number of episodes of sexual intercourse in previous three months without correct use of a condom, number of episodes of sexual intercourse in previous three months whilst drunk, number of episodes of sexual intercourse in previous three months without correct use of a condom whilst drunk, use of other contraceptives,

number of sexual partners in previous three months, diagnosis of an STI in previous three months, emergency contraception use in previous three months and condom use failure in previous three months. Participants were asked to give an approximate answer if they were unsure of the exact number of episodes. These questions were asked in order to get an overall picture of condom use with and without alcohol use and risk-taking sexual behaviour.

2.6.4 Proxy measure of condom use knowledge and skills

Questionnaires at all time-points included a proxy measure for assessing condom use knowledge and skills. This was included as no direct observation of condom use skills would be feasible at follow-up. This proxy measure, the Condom Use Skills Checklist (CUSC) devised by Stanton *et al.* (2009), was developed with high-risk Bahamian youths and adults. In order to tailor this measure for use with the participant group one item (use a lambskin condom) was removed from the original 17-item scale. Cronbach's alpha scores for adults using the CUSC have been previously reported as 0.63 overall (0.80 for correct answers and 0.47 for incorrect answers; Stanton *et al.*, 2009). The amended 16-item checklist required participants to identify eight statements on how to correctly use condoms.

2.6.5 Self-efficacy to use condoms

The National Institute of Mental Health's Condom Use Self-Efficacy Scale tested by Peterson and Gabany (2001) was included at all three time-point questionnaires. This particular measure was chosen above other similar measures as it included more items addressing the

role of alcohol in condom use and had higher demonstrable Cronbach's alpha scores, reported to be 0.94 (Peterson and Gabany, 2001). This measure was developed to measure the degree of confidence in condom use and has been previously tested on college students. The measure includes six factors – risk avoidance, condom placement, persuasion, eroticising condoms, persuasion under the influence of alcohol and substance use, and condom availability – and has been previously found to show that students with a higher degree of self-efficacy are more likely to use condoms consistently.

2.6.6 Intentions to use condoms

In order to take into account participants' intentions to use condoms if the opportunity did not arise between the intervention and the follow-up period, a measure of condom use intentions was also included at all three time-points. This comprised four items to assess intention to use condoms during sex with casual partners and four items to assess condom intentions with main partners. These items were lifted from research into protective health values in sexually active adolescents conducted by Rosengard *et al.* (2001). The internal consistency for these items has been previously reported to be 0.90 and 0.93 for casual and main partners respectively.

2.6.7 Alcohol use

In order to identify hazardous and harmful alcohol use, the AUDIT tool was used at pre-intervention and at follow-up. This measure has been developed to assess self-reported

alcohol use and reported sensitivity and specificity are documented to be 92% and 94% respectively (Babor *et al.,* 2001). Scores range from zero (a non-drinker) to a maximum of 40. This measure was incorporated not only to provide an additional means of assessing alcohol use (beyond the use of the M-SASQ item comprising one of the eligibility criteria) but also to determine whether alcohol was associated with any other variables.

In summary, measures were chosen specifically to assess the impact of the intervention on condom knowledge and theoretical skills, self-efficacy and intentions to use condoms. In addition, a measure of practical condom skills was incorporated specifically to assess the impact of the skills-based nature of the intervention and to provide an alternative to self-reported data. Free-standing items pertaining to sexual and alcohol behaviour were included to ascertain an overall picture of risk-taking behaviour and alcohol use is assessed over the duration of the intervention.

2.7 Procedure

Ethical clearance from UWE for the rehearsal and research sessions was granted in September 2010. A risk assessment was also carried out as the research was to take place on university premises. As the assistants and facilitating young persons' worker were neither UWE employees nor students, it was necessary for them to adhere to local Health and Safety protocol and receive a handout from the faculty reception. It was also considered appropriate to contact the Domestic team at UWE after each session to tell them that the refuse bins would contain opened condom packets. All research sessions as well as the rehearsal session took place on campus at UWE. Choosing UWE as the host of this research

had pragmatic benefits such as availability of rooms and equipment (e.g. flip-charts and audio-visual equipment) as well as ease of attendance for the participants. This last was thought to aid recruitment.

2.7.1 Session format

The format of every session was kept as similar as possible throughout the study. Participants were required to read an information sheet and provide written consent (Appendix 8 and 9 respectively) before the session commenced. Participants were then given an introduction to the format of the session. This opening introduction was kept consistent between groups and was delivered by the author for all groups. Once consent to take part had been given and the format of the session had been delivered, participants were taken to a separate room one by one for the practical condom exercise, which was scored by an assistant. They were then brought back to the rest of the group. Once all participants had completed the practical condom exercise, participants were given a pre-intervention questionnaire to complete and explicitly told that they did not need to answer questions that they did not feel comfortable answering. Participants were reminded that all questionnaire responses would remain confidential. Once all questionnaires were collected, the session proper began. At the end of the session, participants were required to complete another practical condom exercise and a post-intervention questionnaire under the same conditions as the former. The author concluded each session and provided all participants with a debrief sheet (Appendix 10) with information for onward support pertaining to sexual and alcohol issues. A range of materials were also made available to all sessions, including the rehearsal session. These included

leaflets from Mates the condom manufacturer regarding how to correctly use condoms, alcohol wheels which detailed how many units were contained in various alcoholic beverages from DrinkAware, a broad selection of printed booklets from Brook covering topics such as contraceptive choices, alcohol and sex, and a selection of booklets from the British Heart Foundation covering topics such as CHD. All participants in all sessions were invited to take whatever materials they wished. Participants were provided with the author's and the author's supervisor's contact details and encouraged to contact either of them at any time should they have any queries. A script detailing the contents of the introduction and session conclusion/debrief for all research groups can be seen in Appendix 11. As the scripts demonstrate, the control group were told at the end of the session that they were the control group. It was considered appropriate to offer them the same materials provided to the other two conditions as their session had included no element of safe-sex information but they had performed a practical condom exercise and might have had questions around this. The research sessions lasted approximately 3.5 hours in total, and 0.5 hours was allocated for completion of the follow-up questionnaire, thus participants in the research sessions received four research credits for four hours of research participation. It was made clear to participants that they would only be awarded research credits on completion of the entire study, which included submission of the follow-up questionnaire. However, it was also made clear to students that they could pull out of the research at any time without giving a reason and they did not have to answer any items on the questionnaire that they did not feel comfortable answering.

2.8 Experimental rigour

A number of methodological flaws associated with research in this field identified in the systematic review conducted by the author were addressed where feasible in this research. For example, in order to address one of the fundamental limitations of previous research, participants were required to identify as drinking six or more units of alcohol on one occasion at least once a month (consistent with the previously identified classifications of binge-drinking detailed in chapter 1.1) and in line with previous suggestions advising against binary measures (Leigh, 2002). Thus, a widely accepted definition of binge-drinking was operationalised in order to identify the target population. A three-arm research design was employed with a true control group and all three research conditions were engineered to be equitable in length as well as enjoyment. Similar mediums were employed by all three conditions, such as the use of video clips, flip-chart exercises and group discussion. However, although the intervention condition was concealed from participants at study entry the assistants and facilitators were privy to the intervention condition at all times. Other measures were also incorporated to heighten the robustness of this research. For example, it was considered essential to include a measure of practical condom use skills, which was scored by the same individual for all conditions and to employ the use of a proxy measure of condom use skills in the absence of the opportunity for observed skills at follow-up. Likewise, the author delivered all session introductions and debriefs to maintain consistency. In addition, it was also considered appropriate to enlist the expertise of an external facilitator to deliver the skills-based intervention. This would provide objectivity between the author and intervention delivery.

In summary, the methodological weaknesses identified by the systematic review were addressed where possible for the purposes of the current study in order to enhance robustness.

2.9 Analytical strategy

Data was collected at three time-points in hard copy and was electronically entered into a database. Data were then analysed using the Statistical Package for the Social Sciences (SPSS; version 20.0).

3.0 Results

The research objectives underpinning this study outlined in section 1.6.1 encompassed adapting the former skills-based condom interventional content of Jemmott *et al.* (2005) to produce a compatible intervention programme devised for use with a UK university-based binge-drinking population, conducting a feasibility study of the UK-adapted version and appraising the efficacy of running the UK-adapted version. As such, the following Results section is arranged in two parts. The first part pertains to *outcome evaluation* and what the resultant data and analysis can tell us about the intervention in terms of condom use. The second considers issues pertaining to the *feasibility* of running the study. A summary of the findings concludes this Results section.

3.1 Outcome evaluation

The data presented here seek to explore representativeness and comparability across groups and over time in terms of the outcome measures used. Descriptive data and tests of difference and correlation are explored. A consideration of missing and erroneous data is also included.

Owing to the small sample size of this feasibility study, statistical significance and causality cannot be inferred; however, tentative analysis and observed trends in the data now follow. Data arising from the void control group have been included in some of the following results in order to provide a useful comparison to the other groups. However, owing to the discrepancy in session duration, data from this group have not been included in the tests of correlation and difference.

3.1.1 Preliminary analysis

Data were collected for all three intervention conditions (skills-based, information-only and control) immediately prior to the intervention (time-point 1), immediately following the intervention (time-point 2) and at follow-up (4–7 weeks post-intervention). The data collected from outcome measures included the practical MOCUS, free-standing items pertaining to sexual behaviour, the CUSC, the CUSES, intentions to use condoms and the AUDIT. Table 3.1 demonstrates at what time-points these measures were administered. In terms of evaluating the outcome of this intervention, the most pertinent free-standing items within the questionnaire were those addressing episodes of sex without a condom and episodes of sex whilst drunk without a condom.

Table 3.1: Measure administration

Time-point	MOCUS	Free-standing items (sexual behaviour)	CUSC	CUSES	Intentions to use condoms	AUDIT
1	☑	☑	☑	☑	☑	☑
2	☑		☑	☑	☑	
3		☑	☑	☑	☑	☑

Preliminary analyses revealed that the data did not meet parametric assumptions. Analysis according to time-point and intervention condition suggests that episodes of sex, sex without a condom, sex whilst drunk and sex whilst drunk without a condom predominantly do not follow a normal distribution as determined by significant (< 0.05) Kolmogorov–Smirnov tests. The same was also found for CUSC and MOCUS scores (Appendix 12). Spearman's rho and the Kruskal–Wallis tests (for non-parametric data) were therefore opted for to test for

correlation and differences between variables respectively, the results of which are discussed in due course.

3.1.2 Data relating to participant characteristics and the free-standing items pertaining to sexual behaviour

Data from 27 participants across the four groups (including the void control group) was collected in order to establish the representativeness of the study population. All participants were female psychology students from UWE and aged between 18.5 years to 21.5 years and in the first or second year of study for a bachelor's degree. All participants were recruited from the university participant pool online facility, which awards research credits for psychology research participation. No other incentives for research participation were involved. Participants were required to meet the eligibility criteria stated in chapter 2.5.3 in order to sign up for one of the intervention sessions. The characteristics of the study population are therefore relatively similar, which should be borne in mind in terms of generalising the findings.

The free-standing items pertaining to sexual behaviour are presented in Table 3.2. These items were included to help piece together a picture of the participants' sexual behaviour and highlight indicators of risk-taking behaviour both between groups and over time. There were few differences observed between the intervention groups in terms of sexual and relationship factors, such as other contraceptive use, relationship status and number of sexual partners in the previous three months. Interestingly, all groups demonstrated a decrease in mean number of sexual partners at follow-up. Possible indicators of risk-taking

behaviour such as diagnosis with an STI, use of emergency contraception and condom use failure was minimal. As Table 3.2 generally suggests, there were few differences observed between groups in terms of sexual and relationship factors and indicators of risk.

Table 3.2: Sexual and relationship factors according to intervention group

Group	Time-point	Relationship status	Other Contraception type	STI in last 3 months	Emergency contraception in last 3 months	Condom failure in last 3 months	Mean number of sexual partners in previous three months
Control ***n*** **= 7**	1	Permanent = 3 Casual = 1 Single = 3	Coil = 1 Implant = 2 Pill = 4	No = 7	No = 6 Yes = 1	No = 7	1.43
	3	Permanent = 3 Casual = 1 Single = 3	Coil = 1 Implant = 2 Pill = 3	No = 7	No = 7	No = 7	1.29
Info only ***n*** **= 9**	1	Permanent = 5 Casual = 0 Single = 4	Coil = 0 Implant = 0 Pill = 7	No = 9	No = 9	No = 9	1.67
	3	Permanent = 5 Casual = 1 Single = 3	Coil = 0 Implant = 1 Pill = 7	No = 9	No = 9	No = 8 Yes = 1	1.33
Skills ***n*** **= 8**	1	Permanent = 5 Casual = 1 Single = 2	Coil = 1 Implant = 1 Pill = 5	No = 8	No = 8	No = 8	1.57
	3	Permanent = 5 Casual = 2 Single = 1	Coil = 1 Implant = 1 Pill = 5	No = 8	No = 8	No = 8	1.13
Void control ***n*** **= 3**	1	Permanent = 1 Casual = 0 Single = 2	Coil = 0 Implant = 0 Pill = 3	No = 3	No = 3	No = 2 Yes = 1	1.67
	3	Permanent = 1 Casual = 0 Single = 2	Coil = 0 Implant = 0 Pill = 3	No = 3	No = 3	No = 2 Yes = 1	1.33

Data derived from the free-standing items pertaining to the proportion of sexual episodes including condom and alcohol use were collected in order to identify sexual and alcohol behaviour at base-line and over the duration of the follow-up period, thereby providing insight as to whether the intervention had any effect on actual behaviour with or without the

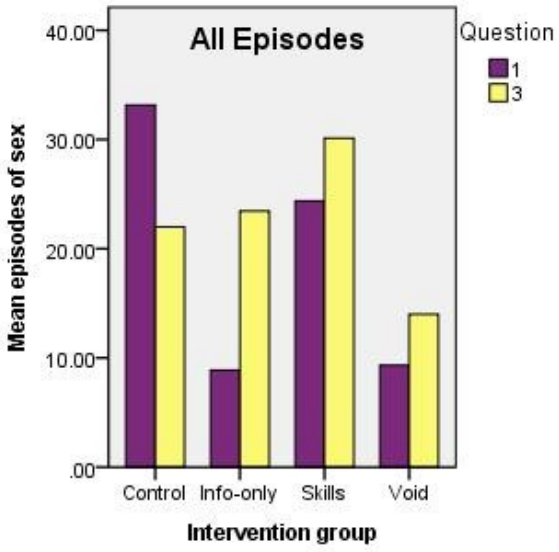
use of alcohol between groups. Table 3.3 below demonstrates mean totals of sexual episodes and *p* values generated by the Kruskal–Wallis test (see Appendix 13). The results of the Kruskal–Wallis test would suggest that there were no significant differences detected in terms of episodes of sex without a condom and episodes of sex whilst drunk without a condom following the intervention. However, differences can be seen pictorially in the mean number of reported sexual episodes (including when condoms were not used and when alcohol was a factor) between the groups and between time-points 1 and 3, from Graphs 1a to 1d. As can be seen, episodes of sex, sex without a condom, sex whilst drunk and sex whilst drunk without a condom increased for the information-only group and skills-based group between time-points 1 and 3 but decreased for the control group. Data pertaining to sexual episodes would therefore suggest that following the intervention participants had more sex including without a condom and while using alcohol for the information-only and skills-based group, which is contrary to the aim of the research suggesting that the intervention was not effective in encouraging actual condom use behaviour.

Table 3.3: Sexual episodes according to intervention group and time-point

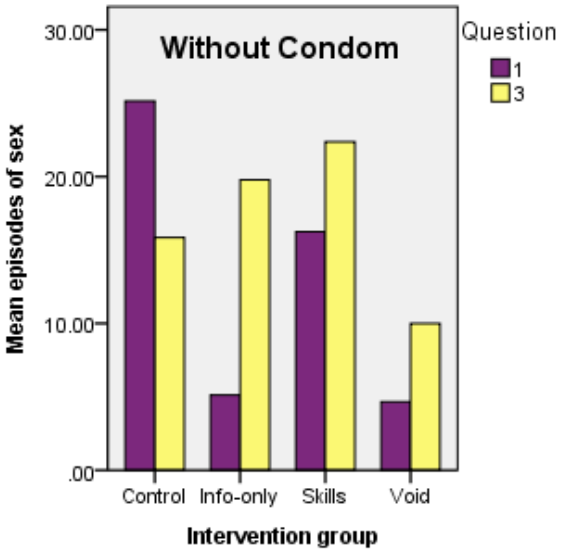
		Number of sex episodes in last 3 months	Number of sex episodes without using a condom correctly in last 3 months		Number of sex episodes whilst drunk in last 3 months	Number of sex episodes without using a condom correctly whilst drunk in last 3 months	
				***p* value**			***p* value**
1	**Info**	8.89	5.11	.300	1.89	0.56	.077
	Skills	24.38	16.25		7.63	5.50	
	Control	33.14	25.14		2.86	1.86	
	Void Control	9.33	4.67		5.00	3.33	
3	**Info**	23.44	19.78	.215	6.56	6.00	.252
	Skills	30.13	22.38		8.50	10.38	
	Control	22.00	15.86		1.86	1.00	
	Void Control	14.00	10.00		4.00	1.00	

N.B The anomaly observed in the yellow boxes is due to an inconsistency in self-reported data
*Significant results are denoted by *. Significance level = <0.05*

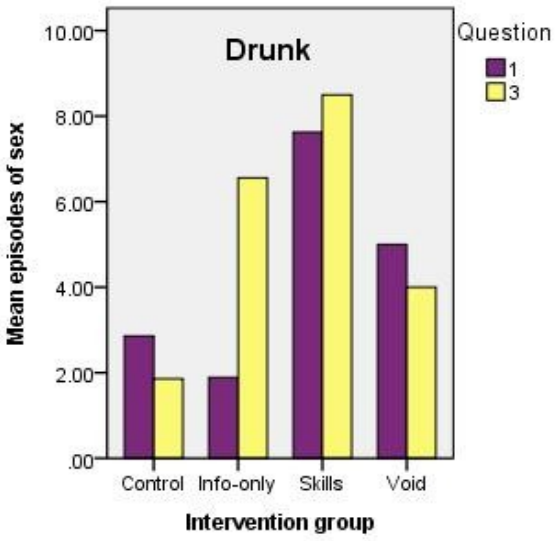
Graph 1a: Mean number of sexual episodes in previous 3 months between time-points 1 and 3



Graph 1b: Mean number of sexual episodes without correct condom use between time-points 1 and 3



Graph 1c: Mean episodes of sex whilst drunk between time-points 1 and 3



Graph 1d: Mean episodes of sex whilst drunk without a condom between time-points 1 and 3

3.1.3 Data relating to standardised outcome measures according to intervention group over time

In order to further explore and compare between groups and over time, data will now be reported detailing changes in the standardised outcome measures in terms of practical and theoretical condom use scores (the MOCUS and CUSC), self-efficacy (the CUSES) and intentions to use condoms. Alcohol use (the AUDIT) is also explored.

Mean total scores were calculated for each of the measures shown in Table 3.4 according to intervention group and time-point with higher scores indicating a greater demonstration of the behaviour or characteristic being measured; for example, higher scores pertaining to practical and theoretical condom use indicate a greater mastery of using condoms as shown by MOCUS and CUSC scores respectively. Data supporting intervention efficacy will be presented initially.

One of the most interesting findings to emerge was that a slight increase in condom knowledge and skills (CUSC) was observed post-intervention within the information-only group and skills-based group which then decreased at time-point 3 for the information-only group but continued to rise for the skills-based group over time, possibly hinting at an increased retention of knowledge for the skills-based group in comparison to the information-only group. This is in contrast to the control group that displayed a decrease in CUSC scores over time (demonstrated by Graph 2a).

Graph 2b also demonstrates the marked increase in MOCUS scores following the intervention for the information-only group and skills-based group. Indeed, as can be seen from the *p* values generated by the Kruskal–Wallis test (Table 3.4), the only significant

difference observed following the intervention was in terms of practical condom skills (MOCUS scores) between time-points 1 and 2 with no other significant differences being detected. It must be noted, however, that this increase in practical condom skills (MOCUS) was found to be remarkably similar between the information-only group and skills-based group compared to the control group, suggesting that having the opportunity to practise condom use skills afforded no additional benefits in this instance.

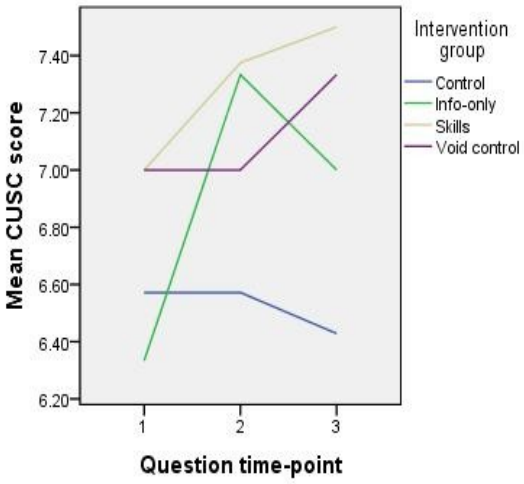
Mean alcohol scores decreased for all groups with the exception of the information-only group, which saw a slight rise at time-point 3.

Table 3.4: Outcome measure scores according to intervention group and time-point

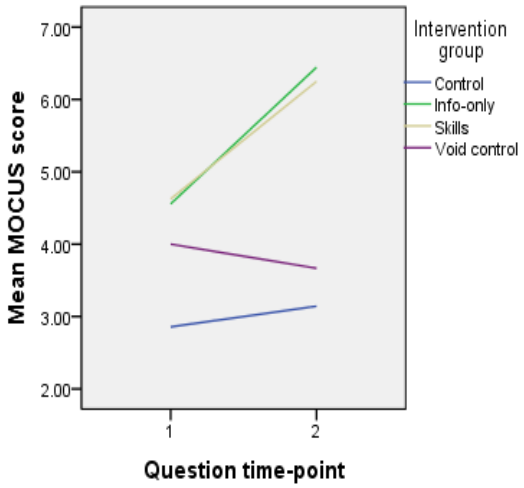
		MOCUS		CUSC		CUSES		Intentions to use condoms		AUDIT
			p value		*p* value		*p* value		*p* value	
1	**Info**	4.56	.037*	6.33	.352	99.67	.608	20.67	.358	11.44
	Skills	4.63		7.00		90.88		20.88		17.00
	Control	2.86		6.57		96.14		25.29		10.14
	Void Control	4.00		7.00		94.33		27.00		24.33
2	**Info**	6.44	.001*	7.33	.074	113.89	.243	26.33	.379	
	Skills	6.25		7.38		103.13		23.50		
	Control	3.14		6.57		99.29		26.71		
	Void Control	3.67		7.00		103.67		28.33		
3	**Info**			7.00	.127	109.11	.405	26.33	.757	12.00
	Skills			7.50		98.75		23.75		14.13
	Control			6.43		95.29		25.86		8.86
	Void Control			7.33		103.00		24.00		24.00

*Significant results are denoted by *. Significance level = <0.05*

Graph 2a: Mean CUSC scores over time



Graph 2b: Mean MOCUS scores over time



Although self-efficacy to use condoms (CUSES) increased post-intervention for the information-only group and skills-based group, this had decreased by the follow-up period, although not to baseline levels. This suggests an improvement in self-efficacy which may decrease over time. Interestingly, increases and subsequent decreases were seen in both the control and void control groups, although to a lesser extent.

A more substantial rise in intentions was observed post-intervention in the information-only group compared to the skills-based group with scores remaining stable between time-points 2 and 3 for both of these groups, suggesting that the skills-based condition afforded no additional benefits in terms of intentions to use condoms over time. Little difference was observed in intentions for the control and void control groups.

In summary, the data reported here would suggest that the participants who took part in this study do not represent a particularly diverse population. This will affect the generalisabilty of the findings. The descriptive data would suggest participants did not vary particularly in terms of sexual and relationship factors and indicators of risk either at baseline or follow-up.

The mean number of sexual episodes with condom use was not improved following the intervention and was found to increase for the information-only group and skills-based group, suggesting that the intervention did not improve actual condom use behaviour. However, factors such as theoretical condom skills, practical condom skills, condom use self-efficacy and intentions to use condoms all improved more for the information-only condition and skills-based condition compared to the control group with sustained changes over time being observed for the skills-based group in terms of theoretical condom use skills. Whilst practical condom skills were found to significantly increase following the intervention they appear to have improved similarly for the information-only group and skills-based group, suggesting that having the opportunity to practise these skills did not afford additional benefits in this instance.

3.1.4 Tests of correlation

In order to identify any relationships between the constructs which may underpin behavioural change, Spearman's rho correlations were generated; significant results are reported in Table 3.5. It would appear that self-efficacy to use condoms (CUSES) is correlated with condom knowledge and skills (CUSC). Also, it would appear that the higher one's self-efficacy to use condoms (CUSES) the higher one's intention to actually use them and in addition the more theoretical knowledge and skills one possesses about condoms (CUSC) the greater one's practical condom skills (MOCUS) will be. A smaller, albeit significant, correlation is observed between condom use self-efficacy and practical condom skills. The AUDIT was not found to be associated with any other construct. This data therefore suggests significant

associations between certain constructs, the implications of which are considered in the Discussion and Recommendations section.

Table 3.5: Significant correlations across intervention groups according to constructs measured

	CUSC	CUSES	Intentions to use condoms	AUDIT	MOCUS
CUSC		.324**			.535**
CUSES	.324**		.494**		.248*
Intentions to use condoms		.494**			
AUDIT					
MOCUS	.535**	.248*			

**Spearman's rho correlation is significant at the 0.05 level (1 tailed)*
***Spearman's rho correlation is significant at the 0.01 level (1 tailed)*

3.1.5 Attrition and erroneous data

This section provides a consideration of missing and erroneous data. A total of 24 participants were recruited to the three intervention conditions and all participants completed the study in full (there was no attrition). With the exception of the observed condom skills practical test (MOCUS) all collated data was acquired via self-report. It is clear from the data that obviously erroneous information was collected, which must be borne in mind. A highlighted example can be seen in Table 3.3. It would also seem that not all participants identified as drinking six or more units of alcohol once a month or more, which

formed one of the eligibility criterion to take part in the study (one participant from the control group and one participant from the information-only group reported drinking six or more units of alcohol less than monthly at time-point 1 as identified by the AUDIT questionnaire). This would suggest that the participants in question either did not meet the eligibility criteria to take part, answered this particular item incorrectly or had a change to drinking habits occur between recruitment and participation.

These examples may suggest that there are further discrepancies in the self-reported data collected, which should be considered, and in terms of future research attempts to move away from a reliance on self-reported data may be beneficial.

In summary, the outcome data reported here would suggest that the intervention did not improve actual condom use behaviour and whilst practical condom skills were found to significantly increase following the intervention they appear to have improved similarly for the information-only group and skills-based group, However, the skills-based condition did appear to show an improvement to theoretical condom use skills in comparison to the information-only group which was observed at follow-up suggesting increased retention of knowledge for the skills-based group which is of interest. Tests of correlation suggest that there are significant relationships between the four constructs measured which may underpin skills-based approaches. The data must be considered in terms of vulnerability owing to its self-reported nature.

3.2 Feasibility

Issues pertaining to the feasibility of running this study are presented here including a consideration of the efficacy of the measures employed, the delivery of the three intervention conditions in terms of how they were perceived by participants and what the findings can tell us in terms of running a future, powered study.

3.2.1 Efficacy of measures employed

This chapter reports tentative analysis of the measures carried out in order to get an indication of questionnaire reliability. This was done by calculating Cronbach's alpha for each subscale where possible as well as calculating alpha scores if particular items were omitted from particular subscales. Likewise, Cronbach's alpha was generated for each measure overall; items which emerged as decreasing overall reliability are highlighted (Table 3.6). The items addressing intentions to use condoms, the CUSES and the AUDIT were subject to Cronbach's alpha calculations. The nature of the measures used to ascertain condom use skills and knowledge (MOCUS and CUSC) rendered this approach inappropriate in this instance.

Table 3.6: Reliability of measures

Measure	Subscale/ factor	Cronbach's α	Items identified as decreasing reliability in each subscale (** Item most likely to decrease reliability in each measure)	Effect on subscale Cronbach's α if item omitted	Overall Cronbach's α	Effect on overall Cronbach's α if most problematic item omitted
Intentions to use condoms with…	Casual partner	.832	*How likely is it that you would not use condoms in the next 6 months with a casual partner*?	.916	.779	.839
	Main partner	.760	***How likely is it that you would not use condoms in the next 6 months with a main partner?*	.955		
CUSES	Multi-faceted risk avoidance	.887	***I can avoid getting high or drunk when I'm going to have sex*	.907	.935***	.938***
	Condom placement	.887	*I can be the one to put the condom on without ruining the mood*	.886		
	Persuasion	.822	*I can use a condom with a partner even if the room is dark*	.879		
	Eroticising condoms	.898	*I can put a condom on (myself/my partner) and enjoy the experience*	.975		
	Persuasion under the influence	.859	*			
	Condom availability	.774	*			
AUDIT	Hazardous alcohol use	.710	*How many drinks containing alcohol do you have on a typical day when you are drinking?*	.871	.848	.863
	Dependence symptoms	.680	*How often during the last year have you found that you were not able to stop drinking once you had started?*	.724		
	Harmful alcohol use	.708	***Have you or someone else been injured because of your drinking?*	.709		

**Only two items in subscale*
***Item most likely to decrease reliability in each measure*
****This Cronbach's alpha score includes item 13 from the CUSES which was previously dropped by the original authors owing to an inferior factor loading*

3.2.1.1 Intentions to use condoms

Items pertaining to intentions to use condoms can be divided into two subscales: "casual" and "main" partners. Cronbach's alpha for each of these subscales were reasonable. However, one item from each can be considered to decrease reliability, and one item in particular can be seen to decrease overall reliability of the measure*: "How likely is it that you*

would not use condoms in the next 6 months with a main partner"? Both items found to decrease subscale reliability were reverse scored items.

3.2.1.2 Self-efficacy to use condoms

Reliability was generally satisfactory for the CUSES measure. The "condom availability" subscale emerged as the weakest of the six, although as this subscale only included two items it is not possible to identify the weaker of the two. The item "*I can avoid getting high or drunk when I am going to have sex"* emerged as the weakest in the "multi-faceted risk avoidance" subscale and the one which would increase overall reliability of the CUSES measure if omitted. This is of concern as it is one of only three items in this measure that address alcohol use in relation to sex. One question in particular that was flagged up by the participants in the rehearsal group as unnecessary and irrelevant in the "persuasion" subscale (*"I can always use a condom even if I'm buying or selling sex or trading sex for drugs"*) was not found to decrease the overall reliability of the subscale or measure in general (yielding a Cronbach's alpha score of .933 if this item were omitted).

3.2.1.3 Alcohol use

The AUDIT measure was included to assess alcohol use at study entry and at follow-up in order to ascertain whether this was associated with any of the other constructs measured. The AUDIT comprises three domains as opposed to discrete subscales; however, the collated data was treated similarly in order to ascertain cautionary reliability. Overall, the Cronbach's

alpha calculated was good. The item *"Have you or someone else been injured because of your drinking"?* from the "harmful alcohol use" subscale emerged as the weakest overall.

To summarise, the measures subject to reliability analysis presented here suggest that reliability as denoted by Cronbach's alpha was good with only marginal gains if the weakest items were removed. In terms of considering feasibility, this would suggest these measures could be implemented, as they were here, in future research.

3.2.2 Intervention comparability across groups

Intervention sessions were designed to be equitable in length as well as in enjoyment across conditions for participants to reduce the potential for any effects being due to discrepancies in intervention delivery as opposed to content. To assess participation enjoyment across conditions, participants were required to complete an evaluation form at the conclusion of each intervention session. This was done to collect information about how the participants from each group viewed the session they had just taken part in. The form comprised six items addressing how enjoyable the session was, how interesting it was, whether it was beneficial to complete with other participants, whether they had learnt information of relevance to them, whether they had learnt anything that might benefit their health and whether they would recommend the session to others. Responses were gathered on a five-point Likert Scale with 1 denoting "yes" to agree to 5 denoting "no" to disagree. Scores can be viewed in Table 3.7.

Table 3.7: Session evaluation scores

	Control *n* = 7 (mean scores)	Info only *n* = 9 (mean scores)	Skills *n* = 8 (mean scores)	Void control *n* = 3 (mean scores)
This session was enjoyable to me	1.29	1.78	1.44	1.67
I found this session interesting	1.43	1.78	1.25	1.00
Completing this session with others was beneficial	1.29	1.67	1.13	1.67
I have learnt things today which are relevant to me	1.29	1.78	1.25	1.33
I have learnt things today that may benefit my health	1.14	1.67	1.13	1.00
I would recommend this session to others	1.14	1.44	1.25	1.00
Total score per group	7.58	10.12	7.45	7.67

As Table 3.7 demonstrates, sessions were perceived reasonably equitably across the intervention groups with the exception of the information-only group. These scores would suggest that the control group did not perceive their session on CHD to be of any less enjoyment, interest or relevance than the other groups. Data from the void control group is also included for comparison. The three participants in this session do not appear to have viewed their session less favourably than the other groups despite their session falling quite substantially short in terms of duration. In terms of feasibility, these evaluation scores would suggest that it is possible to devise an intervention programme that is acceptable and enjoyable for female, university undergraduate students designed to encourage condom use using existing resources.

3.2.3 Support offered from feasibility findings in running a powered study

This section seeks to establish what feasibility issues have been uncovered by this study and what this feasibility study can offer in terms of support for running a powered study drawing

on evidence and findings presented in sections 3.1 and 3.2. A concluding chapter summarises this Results section.

Whilst there is sound justification for assuming that a female, binge-drinking, undergraduate population may benefit from this intervention, the lack of generalisability of using this particular sample must be considered. It is also important to note that descriptive data from the free-standing items pertaining to sexual and relationship factors does not indicate high levels of risk-taking behaviour, which may also limit the effectiveness of the intervention in this given population. These issues would need to be addressed if running a powered study. This feasibility study does demonstrate that an intervention could be devised using existing materials which were deemed enjoyable, interesting, beneficial and relevant to the sample population. In addition, the three intervention conditions were perceived relatively equitably across groups, which could also help inform a powered study. The reliability of measures for those assessed suggests that those used were appropriate and could be employed in a larger study. The finding that the AUDIT measure did not appear to be significantly associated with any other measured constructs suggests that this could be omitted. The presence of inconsistencies in the data highlights the questionable accuracy of self-reported data and a powered study would likely benefit from data gathered more objectively where possible.

The effectiveness of the skills-based component of the intervention and implications for a powered study will now be considered. Whilst there is a suggestion that condom use knowledge and theoretical skills may benefit from the skills-based condition in terms of retention over time compared to the information-only condition, the same cannot be said for intentions to use condoms, practical condom skills or self-efficacy to use condoms as although these all improved post-intervention compared to the control group, outcomes

were not markedly different from the information-only group, suggesting that having the opportunity to practise skills afforded no additional benefits in this instance. Likewise, although the Kruskal–Wallis test identified a significant difference post-intervention for practical condom skills, the same was not found for the other constructs measured. These findings must also be considered alongside the data that identified more episodes of sex without a condom and more episodes of sex whilst drunk without a condom post-intervention for the skills-based and information-only groups, which was contrary to the research objectives.

In summary, whilst this study has proved beneficial in terms of highlighting the feasibility issues of conducting a powered study, the resultant findings in terms of outcome evaluation – broadly consisting of two themes (that the theoretical constructs can be improved by the intervention content although actual condom use was not found to improve and that few differences were observed in outcomes between the information-only group and skills-based group) – suggest that the intervention in its current format and the framework it was delivered in are not efficacious. A discussion as to why this may be and recommendations for future research will now follow.

4.0 Discussion and Recommendations

The following Discussion and Recommendations section provides a brief summary of the key findings to emerge from this feasibility study. The implications of these key findings are then considered, with reference to the wider literature. Finally, recommendations for future research are covered in terms of the usefulness of the current feasibility study.

4.1 Summary of key findings

As the concluding parts of the preceding Results section suggests, there are two key themes to emerge from this study:

1. Whilst the theoretical constructs explored in this study (self-efficacy, intentions, practical condom skills and theoretical condom knowledge and skills) appeared to increase following the intervention, actual condom use behaviour did not.

2. The observed changes to theoretical constructs on the whole do not appear to vary particularly between the information-only group and the skills-based group.

These two key themes will now be considered in turn with reference to the relevant literature.

4.1.1 The disparity between enhanced theoretical constructs and decreased condom use

Although more marked improvements were observed in terms of practical condom skills (MOCUS), theoretical condom knowledge and skills (CUSC), condom use self-efficacy (CUSES)

and condom use intentions for the information-only group and skills-based group following the intervention (in comparison to the control group), there were no similar observed increases in actual condom use. Although this is consistent with previous research (Paul-Ebhohimhen, Poobalan and van Teijlingen, 2008), participants in the current study reported an increase in sex episodes, more sex episodes without a condom, more episodes of sex whilst drunk and more episodes of sex whilst drunk without using a condom (skills-based and information-only group), whilst the control group demonstrated a decrease in all of these post-intervention. Possible explanations for this unexpected and undesirable outcome will now be considered and will include a discussion about bridging the gap between theory and practice, alcohol-sex expectancies, study design and participant characteristics.

4.1.1.1 Bridging the theory and practice gap

Although this intervention was not explicitly based on any one particular social cognition model, in many cases the theoretical constructs explored are similar to those inherent in such models, and issues around their predictive utility are similar. The failure of social cognition models in predicting actual behaviour is well documented (Sutton, 1998). In terms of the current study, the usefulness of intentions to use condoms, self-efficacy and theoretical condom knowledge and skills in predicting behaviour will now be considered.

Intentions have previously been reported to be "prerequisite but not sufficient to realise actual behaviour change" when considering condom use (James *et al.*, 2005, p. 165). Indeed, the intention–behaviour gap is a recognised flaw of social cognition models and the formation of implementation intentions has been suggested as a means of bridging the gap

from theory to practice (Gollwitzer, 1993). With regard to condom use, van Empelen and Kok (2008) found that intentions to use condoms did not go far enough to prepare students for condom use and, instead, suggest condom interventions should aim to encourage the buying and carrying of condoms. More specifically, De Vet *et al.* (2011) found that when women were asked to form implementation intentions for condom use generally it was difficult for them to do so. However, when women were asked to form implementation intentions for preparatory behaviours such as buying, carrying or discussing condom use, the results were quite different. Implementation intentions for preparatory behaviours were of better quality than the former and, in addition, the women who formed strong implementation intentions for preparatory behaviours tended to view them as more useful and were more committed to them. At two-month follow-up, it was also found that this perceived usefulness and commitment to plans predicted preparatory condom behaviour. The durability of contraceptive implementation intentions (including condoms) has also been demonstrated over a follow-up period of two years (Martin *et al.,* 2011). The findings of van Empelen and Kok (2008), De Vet *et al.* (2011) and Martin *et al.* (2011) are of relevance to the current study in that the current intervention content focused on condom skills as opposed to preparatory behaviours and the formation of implementation intentions such as buying and carrying condoms. This may have contributed to the lack of observed condom use at follow-up by an inadequate bridging of the intention–behaviour gap. Whilst there is sound justification for including a measure of self-efficacy (Bandura, 2004) and although Sheeran, Abraham and Orbell (1999) found self-efficacy to use condoms and condom use to be correlated, the same was not seen in the current study, as reported condom use did not increase following the intervention and self-efficacy scores increased for all groups. The usefulness of self-efficacy

as a predictive variable is therefore questionable. As Lindemann and Brigham (2003) suggest, if one's belief that one can use condoms is inaccurate then measuring self-efficacy is likely to be unhelpful. This is supported by Langer, Zimmerman and Cabral (1994), who found that in a large sample of genitourinary clinic participants, mean condom scores were 60% correct even though 89% of participants reported they were "very sure or somewhat sure" (p. 685) they could put on and take off a condom correctly, leading the authors to suggest that perceived self-efficacy is not a reliable marker of demonstrable condom skills. This suggestion may provide some explanation as to why a change to condom use behaviour was not observed.

In terms of theoretical condom knowledge and skills, Sheeran, Abraham and Orbell (1999) found a small correlation between knowledge of HIV and AIDS and condom use in their meta-analysis and suggest that knowledge on its own is not a sufficient target for preventative initiatives, thus highlighting a knowledge–behaviour gap. In terms of knowledge of how to theoretically use a condom and possessing the practical skills of how to use them, it is possible that possessing this knowledge alone is not sufficient to translate into actual condom use behaviour and again highlights the importance of the issues raised above in terms of preparatory behaviours.

In summary, whilst the increase in theoretical condom knowledge and skills, intentions, self-efficacy and practical skills following the intervention is a positive outcome, the lack of observed improvements to actual condom use is disappointing and may in part be explained by the predictive qualities of the variables measured. However, other arguments are also considered here and will be reported.

4.1.1.2 Alcohol-sex expectancies

The intervention content presented in this study attempted to increase condom use in a binge-drinking sample of females. To this end, the intervention contained material aimed at highlighting the adverse effects that alcohol could have on one's decision or ability to use condoms. This approach is consistent with the suggestions put forward by Norris *et al.* (2009), who advise "prevention interventions should include information about alcohol effects on cognitions that may lead to ineffective condom negotiation and unprotected sex" (p. 20). Indeed, this would seem an intuitive view. However, this view does seem to be at odds with research that has looked at the role of alcohol-sex expectancies and may give an insight into why actual condom use decreased following the intervention.

LaBrie *et al.* (2005) define alcohol expectancies as "beliefs and ideas about the positive and negative effects that alcohol has on an individual's behavior" (p. 260), with a further definition of sex-related alcohol expectancies to cover beliefs pertaining to the role of alcohol in sexual disinhibition, condom use and sexual arousal, for example. Walsh *et al.* (2011) found 67% of women reported some binge-drinking during the first month of college and that those with expectations that this drinking would lead to unsafe sex reported less frequent condom use. Corbin and Fromme (2002) have also found alcohol-sex expectancies to be associated with decreased condom use at first intercourse with an overall greater effect being observed early on in relationships. They go on to suggest that expectancies can be considered "a fairly robust moderator" (p. 235) when considering the relationship between condom and alcohol use.

These findings may be of relevance to the findings of the current study in that the information-only and skills-based group in the current study were required to consider the potential effects of alcohol in relation to condom use. Both of these groups reported more sex at follow-up without a condom and whilst drunk, whereas the control group who were not required to consider the role of alcohol in relation to condom use demonstrated the reverse. The possibility that the intervention content prompted a situation that fuelled alcohol-sex expectancies must therefore be considered. The view that cognitions can be unintentionally altered is also discussed by Ogden (2003), who suggests that "all question asking can also bring about change" (p. 427) and uses the example that at times question asking is used as an active intervention in some cases and for descriptive purposes in others. This logic would therefore suggest that the measures used in the current study pertaining to the role of alcohol in the decision to use condoms may have inadvertently altered the participants' views that they held on the influence of alcohol in condom use. This potential self-fulfilling prophecy in combination with intervention content may have strengthened negative alcohol-sex expectancies and may go some way to explain the lack of condom use seen at follow-up.

As Leigh (2002) suggests, "health education messages that are based on a causal model may even have paradoxical harmful effects, if highlighting a link between drinking and risky sex gives people a convenient excuse for engaging in risky behaviours" (p. 481). The above evidence must therefore be borne in mind when considering why condom use was found to decrease at follow-up.

4.1.1.3 Study design

The lack of condom use observed at follow-up may in part be due to the short follow-up period of the current study (4–7 weeks). Jemmott *et al.* (2005) report no intervention effects of their condom skills-based programme at three-month follow-up (in terms of unprotected sex), although this was not the case at 12-month follow-up. The apparent delayed effect of their intervention prompted the authors to suggest that this may have arisen from participants finding it hard to incorporate their newly acquired condom skills into existing relationships, but as these relationships came to an end and new ones were established, windows of opportunity to put these skills to use may have presented themselves. This may explain why condom use was not found to improve following the current intervention and is supported by the finding that intentions to use condoms remained stable up until follow-up for the information-only group and skills-based group. Lally *et al.* (2010) suggest that interventions designed to encourage habit formation may need to provide continued support to reinforce repetition. These findings are supported by a review of sexual health interventions conducted by Shepherd *et al.* (1999), who quote Prochaska *et al.* (1994) and Bandura (1990), with the former suggesting it can take six months for health behaviour change to become routine and the latter suggesting that health messages must be reinforced over time if behavioural change is to be maintained. Such suggestions may imply that the current study would be improved if condom use were prompted frequently over time with the addition of booster sessions integrated into the intervention content.

4.1.1.4 Participant characteristics

The contribution of participant characteristics in terms of providing an explanation of the lack of actual condom use at follow-up will now be considered. Proposed explanations include the age of participants, risk status and use of alternative contraception.

In a review of studies aimed at improving contraception use, delaying intercourse and reducing unintended pregnancies, DiCenso *et al.* (2002) found minimal effectiveness of these interventions and suggested that targeting interventions at lower age groups would be more beneficial. This is also supported by Sheeran, Abraham and Orbell (1999), who suggest that interventions to promote condom use should begin early so as to encourage condom use at first intercourse. Indeed, Shafii *et al.* (2004) also found that in a large sample of American adolescents condom use at first ever sexual intercourse was associated with a two-fold increase in condom use at most recent intercourse. This supports the view that early intervention is particularly useful in promoting future condom use and suggests it is a possibility that the lack of condom use increase observed at follow-up is due, in part, to the participant group not being of optimum age for intervention.

Jemmott *et al.* (2005) report overall success for their skills-based intervention aimed at 12- to 19-year-old adolescent girls, although it must be remembered that this sample was substantially different from the current sample, namely in terms of comprising participants more at risk of unplanned pregnancy and STI/HIV acquisition. Morrison-Beedy *et al.* (2005) also report positive outcomes for their IMB intervention, which included "at-risk/economically disadvantaged" (p. 6) 15- to 19-year-old females despite a modest follow-up period of three months. Likewise, Walsh *et al.* (2011) report that in a sample of 18-year-

old college students, condom use decreased less over the first year of college if they demonstrated greater academic achievement and came from a family of greater wealth. Indeed, the influence of socioeconomic factors has been acknowledged previously (Department of Health, 2013; Department for Education and Skills, 2006), and whilst socioeconomic data was not collected for the current sample it is prudent to say that the university sample in this study does not represent those most at risk overall. However, in terms of what characteristics may have the most weighting on actual condom use, alternative forms of contraception use must now be considered.

The majority of participants in the current study were taking some other form of contraception, such as the contraceptive pill, intrauterine device and implant. Whilst some women generally may prefer to adopt a dual approach to contraception (using condoms in conjunction with another method), it is likely that the predominant reliance on other methods of contraception negatively affected reported condom use at follow-up. This assertion is supported by Corbin and Fromme (2002), who found that use of the contraceptive pill was associated with a reduction in condom use during first intercourse with a regular partner. Likewise, Walsh *et al.* (2011) found condom use to be negatively associated with alternative contraceptive use. As Sheeran, Abraham and Orbell (1999) also report that greater condom use is associated with a favourable attitude towards combined condom and contraceptive pill use, promoting a dual approach may also prove efficacious for future research. This approach may encourage longer-term behavioural change in condom use over time. In considering the above evidence, focusing the intervention on a younger sample that represents a demographic at greater risk of STIs and unintended pregnancy

particularly before they have settled on an alternative form of contraception would seem appropriate.

In summary, the predictive abilities of the variables measured, the role of alcohol-sex expectancies, study design and participant characteristics may all play their part in the lack of observed condom use at follow-up. However, the only argument that goes some way to explain decreased condom use at follow-up is that presented by the role of alcohol-sex expectancies. These suggestions, however, must be considered in terms of the small sample size, but all explanations discussed provide useful recommendations for future research.

4.1.2 Explanations for the observed differences or lack of differences observed between the information-only and skills-based groups

As the chapter above indicates, positive increases were observed in terms of practical condom scores (MOCUS), condom knowledge and theoretical skills (CUSC), self-efficacy to use condoms (CUSES) and intentions to use condoms following the intervention for the information-only group and skills-based group in comparison to the control group. The most interesting finding pertinent to the aims of this study was that CUSC scores continued an upward trend to time-point 3 for the skills-based group, possibly hinting at the benefits of skills-based activities in terms of retention of knowledge. However, Table 3.4 offers few differences between the skills-based and information-only groups and the only significant differences observed were in terms of MOCUS scores between time-points 1 and 2. These latter findings are consistent with the work of Jemmott *et al.* (2005), who report no statistically significant differences in terms of variables such as intentions to use condoms

and skills beliefs between their skills-based and information groups. However, these findings will now be considered in terms of possible explanations and implications.

4.1.2.1 The effects of skills-based learning in terms of retention of knowledge

The upward trend of CUSC scores for the skills-based group is particularly encouraging in terms of the aims of this feasibility study. This finding is consistent with previous research, which found success using experiential learning and social learning approaches (e.g. Choi *et al.*, 2008), although an extended follow-up period would be required to assess the longevity of this effect. In terms of conducting a powered RCT, a process evaluation identified as good practice in complex interventions (Oakley *et al.*, 2006) would be beneficial in order to identify the active component in the skills-based approach.

4.1.2.2 Strength or nature of skills-based component

One possible explanation for the lack of apparent differences between the skills-based and information-only groups is the possibility that the "skills" based element was not powerful enough. The current intervention content comprising the skills-based session attempted to enhance safe-sex skills in terms of negotiation and condom skills by allowing participants to rehearse these. Donohew *et al.* (2000) suggest that sufficient attention be paid to the rehearsal of sexually risky situations in an attempt to increase the automaticity of appropriate responses should a sexually risky situation present itself. Although the intervention content of the current study did attempt to address this in terms of the role-

play and safe-sex negotiation strategies included, it is possible that this particular element of intervention content was not pronounced or potent enough to achieve more noticeable effects. In addition, whereas practical condom skills could be assessed by use of the MOCUS, a measure to test changes to negotiation skills was not incorporated. Shepherd *et al.* (1999) report a scarcity of research acknowledging the lack of power that is often experienced by women in sexual relationships that can affect sexual negotiation and decisions relating to condom use. Future research may therefore benefit from a more focused and fastidious evaluation of skills to enhance assertiveness and enhance one's power in sexual relationships in order to facilitate condom use in conjunction with some form of process evaluation in order to ascertain what elements of the intervention are successful.

To summarise, whilst the finding that the theoretical constructs increased following the intervention is a positive outcome, the lack of improvements in condom use is disappointing. At the same time, whilst the skills-based intervention appeared to yield no additional benefits compared to the information-only condition, it is encouraging to note the exception to this which was improved theoretical condom knowledge and skills at follow-up. In terms of the aims of this feasibility study, this piece of research provides valuable data as to the ideal parameters of a powered trial in terms of study design and participants required, as well as guiding intervention content and measurement. Recommendations for future research based on these considerations now follow.

4.2 Recommendations

Recommendations arising from this feasibility study will draw on those highlighted above as well as other observations arising from the execution of this research and will seek to inform the parameters of a powered trial as set out in the research objectives. These recommendations can be broadly separated in terms of study design and data collection, recruitment and participants, intervention content and delivery, and measures and analysis.

Study design and data collection: A follow-up period was essential in terms of allowing behavioural changes over time to be observed as mentioned previously; however, an extended follow-up period is recommended for future research. Not only would this provide an opportunity for condom skills to be utilised in future relationships (as opposed to current ones, which may be difficult), it would also allow the opportunity to see whether the most promising finding of this study (the continual upward trend of retention of knowledge for the skills-based group) stood the test of time. In addition, whilst an RCT design was recognised as the most robust format for the current study, it was not possible to truly randomise participants or for the study to be double-blinded. It is therefore recommended that a powered trial adopt a different means of recruitment in order for this crucial element of study design to be appropriately addressed whilst considering the issue of equipoise (Petticrew *et al.*, 2013) and Jadad scoring (Jadad *et al.*, 1996). The methodological weaknesses identified in the systematic review as well as those noted in previous research should guide design and reporting issues (Oringanje *et al.*, 2009).

Recruitment and participants: As mentioned previously, one of the possible explanations put forward for a lack of observed condom use at follow-up centres on the participant

characteristics and eligibility criteria for taking part in the study. It is therefore recommended that a powered trial focus on a younger, more at-risk demographic that has preferably not settled on an alternative form of contraception. This could involve a clinic, school or youth group sample. Indeed, whilst the online participant pool was an effective means of recruiting this particular demographic, a number of limitations were associated with this method of recruitment. As research credits were required to be submitted towards the end of the academic year, the follow-up period for this study was restricted. This was also negatively affected by difficulties recruiting initially (owing to a more stringent eligibility requirement necessitating no alternative forms of contraception). Accessing a different demographic of young women in a different setting may help to overcome these obstacles and facilitate a randomised and blind study as well as a more targeted approach. However, an alternative means of recruitment would necessitate a consideration of incentives for study participation. The void control group revealed an invaluable lesson in terms of recruitment and intervention delivery in that it demonstrated how important group size was in delivering the intervention. With just three participants, the intervention fell short quite substantially. It is therefore recommended that should a powered trial take place it would be essential to ensure that group sizes were kept as equitable as possible between conditions by adequately recruiting into sessions in order to minimise an occurrence of this scenario, which could potentially waste valuable resources. Equal sample sizes between intervention conditions is also important in terms of data analysis as Field (2005) suggests that the robustness of statistical tests such as analysis of variance (ANOVA) can be compromised by unequal sample sizes. Thus adequate recruitment and retention is essential for running a fully powered trial.

Aside from recruitment and retention, MRC guidelines (2008) also suggest that feasibility studies consider effect sizes. Indeed, prospective sample size calculations were not performed as part of the design for this study as described in section 2.5.5, rather recruitment was based on the feasibility nature of the research and establishing the parameters of a fully powered trial. In addition, appropriate analysis for the current data was dictated by parametric assumptions, however, in terms of running a powered study, ANOVA may prove a useful means of analysis in order to establish effect sizes if the parametric assumptions of such data was satisfied (Field, 2005). Indeed, based on a typical α value of .05, a medium effect size of .25 (Cohen, 1992) and a total sample size of 24 (*n*), post-hoc power calculations generated by G*Power version 3.0.3 (Faul *et al.,* 2007) for a repeated measures, between factors ANOVA suggests that the current feasibility study lacks sufficient power (power = .22). In terms of a powered trial, and based on given conventional values (α = .05, β = .20, ES = 0.25 and power .80) stated by Cohen (1992) and guided by previous effect sizes (Jemmot *et al.*, 2005), a priori sample size calculations generated by G*Power version 3.0.3 (Faul *et al.,* 2007) for a repeated measures, between factors ANOVA based on three groups and three repetitions suggests 108 participants would be needed for a fully powered trial.

Intervention content and delivery: This research demonstrates that it is possible to put together an intervention using existing national resources designed to encourage condom use that is acceptable for use with university participants and thus addresses one of the fundamental research objectives. The feedback received from participants suggests the content was relevant, enjoyable and beneficial. These findings were generally consistent between the three groups, suggesting that the differing sessions fulfilled their objectives in

being perceived equitably and thus contribute to the robustness of the study design. However, the finding that condom use decreased following the intervention has prompted the suggestion that future research address the role of alcohol-sex expectancies and that implementation intentions and preparatory behaviours are also incorporated. In addition, as discussed, the lack of differences observed between the skills-based and information-only groups suggests that the skills-based element may not have been powerful enough in terms of increasing assertiveness and empowerment. It is therefore recommended that in order to work towards a powered trial the skills-based element of the intervention content be enhanced. Of course, the finding that self-efficacy, intentions and theoretical condom knowledge and skills can be improved as much for the information-only as the skills-based group opens up the possibility of delivering this training remotely (if practical; hands-on experience with condoms affords limited additional benefits). Such an approach would obviously need to bridge the gap between variables such as knowledge, intentions and self-efficacy to actual condom behaviour, however, which again would require further research. Whether a future intervention is delivered in person or remotely, a process evaluation is recommended to identify the active ingredients.

Measures and analysis: The reliability of the measures included in this study was found to be good. The incorporation of a practical skills measure (MOCUS) and a theoretical condom knowledge and skills measure (CUSC) provided an important assessment of demonstrable and non-observable condom use skills, and their future use is recommended. For the purposes of this investigation, the AUDIT tool did not provide useful information so a future study with a similar focus need not incorporate it. The predictive quality of the constructs measured has been discussed, particularly with reference to self-efficacy. In order to

enhance predictive power a firmer theoretical underpinning is recommended in order for testable hypotheses to be explored. Such a move would help address the theory–behaviour gap already mentioned. The free-standing items pertaining to sexual episodes and condom use may not have gone far enough in establishing whether condoms were used correctly, as recent research suggests (Ingham, 2012). In addition, previous research suggests that the methodology employed in alcohol and sex research can bear significantly on the data gathered. Corbin and Fromme (2002) used global, situational and event-level analyses on the same participants and found the results to vary according to the analysis used. A negative association between condom and alcohol use was only found at the event-level, which examines discrete sexual events, whereas a positive association was found (only for new partners) when using the situational level, which considers drinking and sexual activity that occurs simultaneously. Global analyses that explore the frequency of alcohol and unsafe sex found no association at all. These results raise important questions regarding the current research. The methodology employed within the current study that most aptly describes the free-standing items contained within the questionnaires can be described as situational, although it would appear that the results of the current study are at odds with those derived from Corbin and Fromme (2002) in terms of their situational analyses. And yet, as the current study did not unpick the nature of familiarity of partners it is difficult to fully compare results. In considering that situational analyses yielded results for new partners in conflict with those gleaned from event-level methodology, Corbin and Fromme (2002) suggest that the latter method provides greater validity which should be borne in mind when considering future research. The suggestions from Ingham (2012) and Corbin and Fromme (2002) point to the use of diaries such as that reported by Crosby *et al.* (2012) in order to address this issue. The

incorporation of more objective markers such as biologically confirmed STIs is also recommended and supports the previous assertions about recruiting a clinic sample. Should a powered trial take place and the requirements for parametric tests be met (such as normally distributed data and homogeneity of variance), analysis of variance test (ANOVA) would allow comparison between the three intervention conditions and within groups over time (Field, 2005) as previously discussed.

To summarise, this feasibility study is able to provide many recommendations for conducting a powered study with key suggestions focussing on study design, method of recruitment, participant characteristics, the content and delivery of the intervention and choice of measures and analyses.

5.0 Study limitations

The limitations of this feasibility study need to be considered when discussing its results. Many of these limitations have already been discussed in terms of recommendations for future research, such as follow-up period, lack of blinding, randomisation procedures and the reliance on retrospective, self-reported data. The small sample size, although suitable for the nature of this feasibility study, also limits the usefulness of the data. Although there was sound justification for running this intervention in a student population, there are obvious issues around generalisability as the participants represent a narrow demographic. In addition, although sessions were scheduled for when the majority of first- and second-year undergraduate psychology students could attend, there is the possibility that the scheduling of sessions could have unintentionally excluded some participants on the basis of factors such as chosen modules, sporting activities and work commitments. There are also additional limitations in terms of possible confounding variables.

Sensation-seeking has been previously documented by Cook and Clark (2005) and Leigh (2002) as a potential confounding variable. Donohew *et al.* (2000) found that those who were most likely to engage in risky sexual behaviours were those who demonstrated high levels of sensation-seeking and impulsive decision-making. More specifically, alcohol use prior to sex in the last year was found to be significantly related to sensation-seeking, whilst alcohol use prior to the last episode of sex and alcohol use of one's partner prior to the last episode of sex were related to impulsive decision-making. It is not known whether the current sample possessed either high levels of sensation-seeking or impulsive decision-making; however, one of the eligibility criteria for taking part in the study involved participants identifying whether they drank six or more units of alcohol once a month or more. It is therefore a possibility that

the binge-drinking participants making up the current sample were of a high sensation-seeking or impulsive disposition. If so, a potential limitation of this study is that it did not meet the needs of such an audience.

The current study did not measure or consider the use of recreational drugs on condom use, although the effect of drugs as a possible confounder should also be highlighted. The research, however, is mixed in that whilst Yan *et al.* (2007) found adolescents who reported having ever used cocaine or marijuana were less likely to have had protected sex at last intercourse Walsh *et al.* (2011) found that women who smoked marijuana reported more frequent condom use. Also of interest to the current study is the finding that, of the women in their sample who reported smoking marijuana, 85% also reported binge-drinking. As Leigh (2002) points out, different drugs used in different situations give rise to varied effects. Future research is therefore needed to clarify the role of recreational drugs in sexual decision-making (LaBrie *et al.*, 2005).

Whilst the three intervention sessions were designed to be equitable in terms of length and enjoyment in order to reduce bias, there were differences in the delivery of the sessions, owing to who delivered the sessions. For example, the control session was delivered by the author alone, the information-only condition was delivered by the author supported by an assistant and the skills-based intervention session was delivered by the external facilitator (young persons' worker in the field of alcohol and sexual health) supported by the author. Although the author and external facilitator met prior to the intervention session to discuss the session format, content and delivery, it is possible that the delivery styles of the external facilitator and author differed, which could account for some of the differences or indeed lack of differences observed in the outcome data. These decisions were made on a pragmatic

basis according to resources available, although ideally the same external facilitator would have delivered all intervention sessions to minimise bias.

During the academic year that this study took place in, a university-run initiative aimed at promoting student health was also taking place. This initiative largely centred on reducing hazardous drinking in the student population. The presence of this initiative is therefore highlighted as a possible confounder, although this seems unlikely given that the aim of the current skills-based condom intervention was not to directly reduce alcohol and alcohol use was not found to correlate with any other variable.

Despite the study limitations discussed, there are also a number of strengths. All sessions were designed to be equitable using reputable resources. Introductions and debriefs as well as MOCUS scoring were delivered by the same facilitators to maintain consistency. All individuals who contributed to the running of this intervention were female and of a similar age to the participants (5–15 years older than the participants). All were educated to at least bachelor's level and all were employed in an applied field of health or social care. The inclusion of the MOCUS (a demonstrable assessment of condom skills) also provided additional strength. In addition, a three-arm study design with baseline measures as well as participant unawareness of intervention condition at study entry all provided additional robustness. These strengths go some way to address the methodological limitations identified in the included systematic review.

6.0 Conclusion

This feasibility study demonstrates that it is possible to adapt a previously conducted intervention (Jemmott *et al.*, 2005) for use with a UK university binge-drinking, female population. This feasibility study makes an original contribution to health psychology knowledge in that recommendations for a powered trial are offered drawing on both the identified limitations and strengths which have emerged from the execution of this research. Formative work with the rehearsal group suggested the intervention content and questionnaires were acceptable for use with a university sample. Feedback gathered through session evaluations suggests that the participants of this study found the intervention to be enjoyable, interesting, beneficial and relevant. Tentative analysis of this feasibility data suggests that this intervention brought about changes to practical condom skills as well as observed differences to theoretical condom use knowledge and skills, intentions to use condoms and condom use self-efficacy (although not markedly so between the information-only and skills-based groups). No improvements were seen in actual condom use, however. The reasons as to why this may be have been discussed and it is recommended that future intervention content be engineered to incorporate a weightier skills-based element whilst addressing the role of sex-related alcohol expectancies, preparatory behaviours and implementation intentions. Attention should also be paid as to whether the participants are considered to be a sensation-seeking or impulsive audience. A different method of recruitment is recommended which would provide the opportunity to access a different population which may benefit more from this intervention. A few adjustments to study design are also recommended, particularly by extending the follow-up period which would allow the opportunity to explore whether the most promising finding from this study (the

upward trend of theoretical condom knowledge and skills scores over time for the skills-based group) can withstand the test of time.

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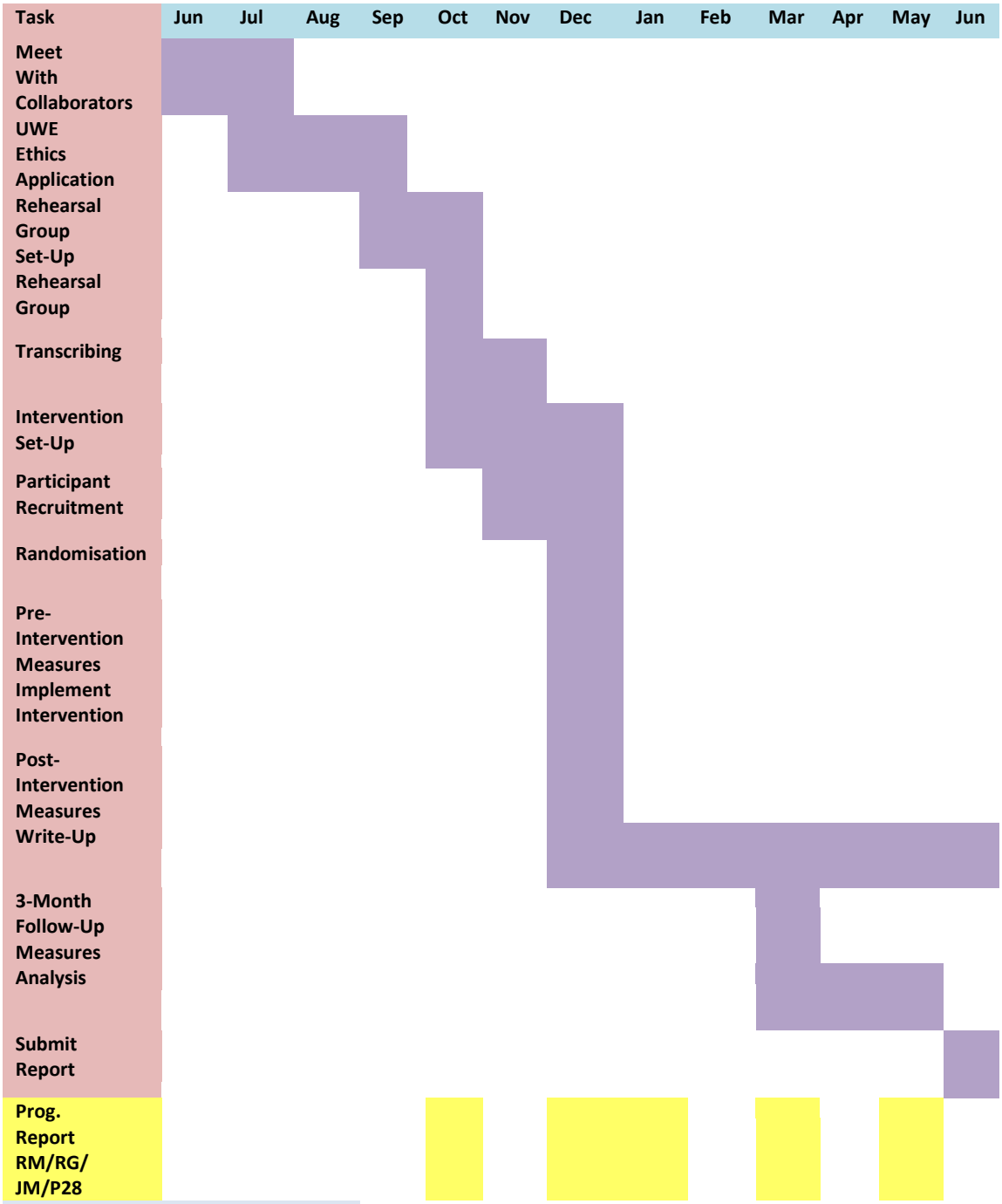
Appendix 1: GANTT Chart



UWE Term Dates			
Year 1 UG	Autumn	20/09/10	17/12/10
	Spring	03/01/11	08/04/11
	Summer	02/05/11	27/05/11
Year 2 UG	Autumn	27/09/10	17/12/10
	Spring	03/01/11	08/04/11
	Summer	02/05/11	27/05/11

Appendix 2: Original Modular Format (Jemmott et al., 2005)

This module outline obtained from www.selectmedia.org is included courtesy of the copyright holders

Sisters Saving Sisters Module Outline: Adolescents Skills Intervention

M1	**Introduction**	**55 Minutes**
A	Introduction & Overview	1
B	Group Introduction	5
C	Creating Group Rules	4
D	Video – "Let's Talk About Sex"	5
E	Video – "The Subject is HIV"	20
F	Myths/Facts About AIDS	10
G	High, Low and No Risk	10
M2	**Vulnerability**	**50 Minutes**
A	Mini Lecture – Why Worry	10
B	Video – "Robert Townsend's Partners in Crime" and Discussion	10
C	Don't Pass It Along : The Transmission Game	15
D	Video – "Jesse" and Discussion	15
M3	**Condom Skills**	**50 Minutes**
A	Barriers to Condom Use	5
B	Video – "Nicole's Choice"	15
C	Condom Use Skills	10
D	Mini-Lecture : Sexual Response	5
E	Making Condoms More Fun	5
F	Condoms Card with a Twist	10
M4	**Negotiation**	**55 Minutes**
A	Video – "Wrap It Up"	10
B	Teaching Negotiation Skills	15
C	Introduction to Role Play	5
D	TEAM Role Plays	25
M5	**Role Play**	**50 Minutes**
A	DYAD Role Plays	25
B	Video – "Are You With Me"	25
	Review	**20 Minutes**
A	AIDS Basketball Game	20

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Appendix 3a: Adapted Session Format (Information-Only and Skills-Based Sessions)

M1	**Introduction – Promoting good sexual health as a valued outcome, introduction of positive subjective norms**	**30 Mins.**
A	Introduction/Overview/Group Rules – Flip-chart exercise	8
B	NHS Video – *Who's got an STI?* (Medley) http://www.nhs.uk/Tools/Pages/sexualhealthvideowall.aspx	4
C	NHS Video – *Understanding chlamydia risk (*Expert) http://www.nhs.uk/tools/pages/sexualhealthvideowall.aspx	4
D	NHS Video – *HIV* (Expert) http://www.nhs.uk/video/pages/medialibrary.aspx?Uri=video%2f2008%2fMay%2fPages%2fHIVexpert.aspx	4
E	20 Questions: Myths/Facts Quiz http://www.avert.org/quizzes.htm	10

M2	**Vulnerability – Strengthening good sexual health as a valued outcome, highlighting personal vulnerability and relevance, reinforcement of positive subjective norms**	**55 Mins.**
A	What is sexual health – Flip-chart exercise www.4thoughtsolutions.co.uk	15
B	NHS Video – *Chlamydia Screening* (Ben and Rosie) http://www.nhs.uk/Livewell/Sexandyoungpeople/Pages/Videochlamydiatest.aspx	6
C	Sex Statistics	5
D	Spin the bottle (adapted Drinkaware Resource) http://www.drinkaware.co.uk/__data/assets/pdf_file/0011/21062/FINAL-alcohol-and-sexual-health-workshop-notes.pdf	20
E	How alcohol works/after drinking alcohol http://brook.org.uk/sex-and-relationships/harmful-situations/alcohol-and-sex	4
F	Transmission – Who are we connected to?	5

BREAK

M3	**Condom Skills – CBT exercise, outcome and self-efficacy expectancies, modelling and vicarious learning (observed condom skills), strengthening of outcome and self-efficacy expectancies via rehearsed condom skills for skills-based group, reinforcement of positive subjective norms**	**45 or 50 Mins.**
A	Condom Tips – http://www.nhs.uk/Livewell/Contraception/Pages/Condomtips.aspx	5
B	Barriers to Condom Use – Condoms don't fit me and other excuses http://www.nhs.uk/livewell/contraception/pages/condomexcuses.aspx	10
C	Condom Demonstration **plus participant practical for skills-based group**	10 + **10**
D	CBT Exercise – Flip-chart exercise	15

M4	**Negotiation/Role Play – Modelling and vicarious learning (negotiation skills), strengthening of outcome and self-efficacy expectancies via rehearsed negotiation skills for skills-based group, reinforcement of positive subjective norms**	**20 Mins.**
A	NHS Video – *Talking about Condoms* http://www.nhs.uk/tools/pages/sexualhealthvideowall.aspx	5
B	Based on: IPPF Condom Negotiation http://www.ippf.org/en/Resources/Contraception/Condom+negotiation.htm**- Interactive role play exercise for skills-based group/facilitator demonstration for Information-only group**	15

M5	**Review**	**5 Mins.**
A	Session conclusion, debrief information	5

Appendix 3b: What is Sexual Health Exercise (4Thought Solutions, 2010)

This exercise outline obtained from www.4thoughtsolutions.co.uk is included courtesy of the copyright holders

Exercise - What is.....Health? / What is Sexual Health?
"Health is not merely the absence of disease or infirmity" *http://www.who.int/suggestions/faq/en/*

This exercise is designed to elicit people's perceptions of what health or being healthy means. We all make observations, assessments of people and often base our reactions, interactions on these perceptions. Be aware that many responses will relate to ill health, it always seems easier to focus on the negative aspects try to refocus negatives into positives.

This exercise can be conducted in two ways: *(you may think of more)*

Preparation – you will need a flip chart or board with the following written on it: **What is.....Health?**
Quarter the sheet/board under this heading into the following four categories

Physical **Social** **Mental / Emotional** **Spiritual/Self Identity**

1. The class is asked to consider how when meeting someone they would assess this persons health.

Responses are recorded on a flip chart some responses will fit in more than one category. Once there are no further responses *(and you have nothing else to add)*, write the word Sexual on the dotted line and ask if the class would delete or change any of the responses they made. The answer is no as health is the same as sexual health.

The idea is to introduce the concept that sexual health is not an entity on its own, but part of our daily life. The exercise opens up and enables discussion on several different fronts. It is also demonstrates that first impression are frequently inaccurate as they are surface, visual based.

For example being physically fit does not mean that disease free, being physically 'disabled' does not mean you are not a sexual being. Being apparently 'healthy or normal' does not mean a person is mentally stable, being mentally disabled does not mean you are unstable. Emotional responses can demonstrate confidence or instability. Being Spiritual means different things to different people, it links into firm self identity, clear religious belief, self awareness. Social to be social means to interact with others.

2. The class is split into groups and each group takes one of the four categories and the groups list their responses on a flip chart piece of paper.
   a. Each piece of flip chart paper is after say 5 minutes passed to the next group in the room to add their response to. Circulate the flip chart papers until each group has had a chance to add their responses. (*this one usually generates the most response)*
   Or b. Each group could then present their list to the class as a whole

Examples of responses you may get, recorded from courses conducted. (*I know some of the phrases are very adult but young people will surprises us all sometimes)*

Physical - Clean Hair, Styled Hair, Bright Eyes, Clear Eyes, Direct Eye Contact, No Bags Under Their Eyes = Sleeps Well, Cleanliness, Clean Smelling, Tall, Good Looking, Muscular, Slim, Good Posture, Clean Cared For Nails, Head Held High, Being Fit, Exercise, Energetic, Mobile / Mobility, Speaks Well, Weight

Mental / Emotional - Direct Eye Contact, Good Posture, Positive Attitude, Balanced, Speaks Well, Balanced Response, Interested, Cheerful, Energetic, Supportive, Good Life Balance, Awareness, Open, Supportive, Empathetic, Stability, Bouncy, Optimistic, Confident, Calm, Happy

Spiritual / Self Identity - Confident, Self Aware, Self Esteem, Openness, Friendly, Positive Attitude, Contented, Karma, Beliefs, Commitment, Communicative, Perceptive, Positive Thinking, Personal Belief, Supportive, Values, Feeling Good

Social- Socialise, Interacts, Communicates Effectively, Face to Face, Online, Working Together, Networking, Attitudes, Doing Things Together, Night Out, Go to the Movies, Shopping, Drinking

Appendix 4: Equipment and Resources

	Source	Skill-based condition	Information-only condition	Control condition
Alcohol wheels	GHNHSFT	☑	☑	☑
Male condoms	GHNHSFT/Project 28/Author	☑	☑	
Female condoms	GHNHSFT/Project 28	☑	☑	
Water-based lubricant	GHNHSFT	☑	☑	
Oil-based lubricant	Author	☑	☑	
Mates condom leaflets	GHNHSFT	☑	☑	☑
Empty wine bottle	Author	☑	☑	☑
Dental dams	Project 28	☑	☑	
Sweets for quiz	Author	☑	☑	☑
Anatomical penis models	GHNHSFT	☑	☑	
BHF booklets	GHNHSFT	☑	☑	☑
Heart models	GHNHSFT			☑
Brook booklets	Project 28	☑	☑	☑
Tissues	Author	☑	☑	☑
Pens, folders for paperwork	Author	☑	☑	☑
Flip-chart	UWE	☑	☑	
Parking permits for assistants and collaborator	Author	☑	☑	☑

Appendix 5: Rehearsal Session Feedback

MOCUS Feedback	**Was this exercise easy to understand? If the answer is "no" what could be done to make it easier to understand?** ▪ "Yes the exercise was easy to understand" ▪ "Yes" ▪ "Yes" ▪ "Yes, to an extent, the wording of the second set of instructions regarding the positioning of the model and condom removal could be more clear" **Was this exercise embarrassing to complete? If the answer is "yes" what could be done to make it less embarrassing?** ▪ "No, I didn't find it embarrassing. However, if you're not that open about having sex I imagine it would be, but I don't think there's any way to avoid this. Not having to do the exercise in front of lots of other people is good" ▪ "Yes, only slightly. Pretending to pull the model penis out was quite funny!" ▪ "Yes, I think it was just me – get embarrassed easily" ▪ "No, very friendly environment!" **Is there any way that the delivery of this exercise could be improved?** ▪ "No, it was explained as fully as need be" ▪ "No, very professional!" ▪ "No, it was fine" ▪ "No, I think the delivery of the exercise was good, aside from the wording as indicated in question 1" **Do you have any other comments regarding this exercise?** ▪ "No. I felt comfortable and the room was private so all in all it was a good way of doing it" ▪ "The ladies dealt with it very well considering it can be a humorous topic" ▪ "No, everything was easy to understand" ▪ "Quite interesting as the role of condom removal is usually down to the male"

20 Questions Quiz	**Did you know some, all or none of the answers?** ▪ "All" ▪ "Some" ▪ "Some" ▪ "Some" **Was the quiz enjoyable?** ▪ "Yes" ▪ "Yes" ▪ "Yes" ▪ "Yes" **Was the quiz an effective way of delivering information?** ▪ "Yes" ▪ "Yes" ▪ "Yes" ▪ "Yes"
What is sexual health exercise?	**Was this exercise appropriate for your age and educational status?** ▪ "Yes" ▪ "Yes" ▪ "Yes" ▪ "Yes" **Was this exercise enjoyable?** ▪ "OK" ▪ "Yes" ▪ "Yes" ▪ "OK" **Was this exercise useful in introducing sexual health as an important part of our well-being?** ▪ "Yes" ▪ "Yes" ▪ "Yes" ▪ "Yes"
Spin the bottle	**Were you able to think of answers to the alcohol scenarios?** ▪ "All" ▪ "All" ▪ "Some" ▪ "Some" **Was this activity enjoyable?** ▪ "Yes" ▪ "Yes" ▪ "Yes" ▪ "OK" **Was this activity a useful way of facilitating thinking around drinking alcohol?** ▪ "Yes"

	▪ "Yes" ▪ "Yes" ▪ "Yes"
Condom demo and practical	**Did you learn any new information or skills from the condom demonstration and practical exercise?** ▪ "Info" ▪ "Info" ▪ "Info/skills" ▪ "Skills" **Was this activity enjoyable?** ▪ "OK" ▪ "Yes" ▪ "Yes" ▪ "Yes" **Was this activity a useful way of demonstrating how to use condoms?** ▪ "Yes" ▪ "Yes" ▪ "Yes" ▪ "Yes"
CBT flip-chart exercise	**Did this exercise demonstrate the relationship between thoughts, feelings and behaviour in a sexual situation?** ▪ "Yes" ▪ "Yes" ▪ "Yes" ▪ "Yes" **Was this activity enjoyable?** ▪ "OK" ▪ "OK" ▪ "Yes" ▪ "Yes" **Was this activity useful to you?** ▪ "Yes" ▪ "Yes" ▪ "Yes" ▪ "Yes"
Condom negotiation and practical	**Did you learn any new information or skills from the condom negotiation demonstration and practical?** ▪ "Info" ▪ "No" ▪ "Info/skills" ▪ "Skills" **Was this activity enjoyable?** ▪ "Ok" ▪ "Yes" ▪ "Yes"

	▪ "Yes" **Was this activity a useful way of demonstrating how to negotiate condom use?** ▪ "Yes" ▪ "Yes" ▪ "Yes" ▪ "Yes"
Questionnaire feedback	**Are there any questions that did not make sense to you?** ▪ "No, I understood them all. They are worded very well" ▪ "Part C, Q6 – I don't understand why the question would need to be asked as I don't think many people would do that. Part E, Q6 – I didn't understand what is meant by first drink" ▪ "They all made sense, however, the questions about current use of condoms with partners (questions 18–26) were a little repetitive" ▪ "Part C, all questions, because they were worded 'I can' means you must answer to what extent you are able, not to what extent you actually would do or say something**"** **Are there any questions which you feel could be re-worded to make them more acceptable to participants?** ▪ "Part C, question 6, perhaps there should be a N/A box to tick" ▪ "I think all questions are fine. When you sign up to a study that you know is about sexual behaviour, your prepared for what's being asked in the questionnaire and nothing seemed inappropriate" ▪ "I found many of the questions irrelevant because I am on the pill. In order for you to get more valid data perhaps more boxes about current relationship condition would help. For example, my circumstances are such that I have just finished a 2 year relationship and my sexual pattern will now change. If I had not told you this my result may seem like an outlier" ▪ "Part C, Q6, this is a question that would not apply to many people, it also does not fit with the theme of the overall section" **Does the front cover provide you with all the information you require?** ▪ "Yes" ▪ "Yes" ▪ "Yes, it's very good, clear and precise" ▪ "Yes, the information is clear and informative" **Are you happy with the layout of the questionnaire?** ▪ "Yes, it's very clear and easy to read and well laid out" ▪ "Yes, the layouts fine" ▪ "The questions were fine. Perhaps a 'not applicable' box would help" ▪ "Section E is unclear regarding where you are supposed to tick, some boxes do not have enough room" **Any other comments?** ▪ "None"

	▪ "Quite long, maybe mix the questions up a little as I found myself answering '5' a lot, and to make sure people are reading the question properly if you mixed up the scale answers may be more accurate" ▪ "The majority of the questionnaire regards actions and thoughts when using condoms, however, participants aren't asked whether they actually use them"
Any other feedback?	▪ "Fun, informative activities but lots of spare time between activities"

Questionnaire 1

You are being asked to complete this questionnaire as part of a study that you have agreed to take part in. The questions cover various aspects of your sex life and alcohol use as well as other attitudes and beliefs you might have.

If you do not know the exact answer to any questions then it is fine to give an approximate answer. Your answers will remain completely confidential.

Many of the questions ask you to circle the most relevant number to show your opinion. Please answer the questions as best you can. Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought-out response. The questionnaire should only take around 15-20 minutes to complete.

You will be asked to fill in this questionnaire prior to the health education session starting and you will be asked to complete another questionnaire including an evaluation form immediately after it finishes. You will also be posted a questionnaire in three months to complete.

Before you complete the questionnaire you will be asked to complete a practical condom exercise.

If you would like any more information, or wish to change your mind, please contact

Zoe Hurrell or Rachel Gillibrand on Tel:0117 32 83385

Thank you for completing this questionnaire

Practical Condom Exercise

“Please demonstrate how to apply a condom using this model”.

“Now I would like you to rotate the model so that it is parallel to the floor as though the penis is still in the partner. Please demonstrate what to do with the condom as the penis is removed from the partner. Then, demonstrate how to remove the condom from the penile model”.

Part A

1. How old are you (mm/yyyy)? _ _/_ _ _ _

2. Please describe your relationship status (please tick ☑)

   Single ☐

   Casual relationship ☐

   Permanent relationship (main partner) ☐

3. How many episodes of sexual intercourse have you had in the last 3 months? (please give an approximate answer if you do not know for sure) ☐

4. How many episodes of sexual intercourse have you had without using a condom correctly (from the start of sex through to the end of sex) in the last 3 months? (please give an approximate answer if you do not know for sure) ☐

5. How many episodes of sexual intercourse have you had whilst drunk in the previous 3 months? (please give an approximate answer if you do not know for sure) ☐

6. How many episodes of sexual intercourse have you had without using a condom correctly (from the start of sex through to the end of sex) whilst drunk in the last 3 months? (please give an approximate answer if you do not know for sure) ☐

7. Do you use another form of contraception?

   Yes ☐ Please state.....

   No ☐

8. How many sexual partners have you had in the last 3 months? ☐

9. Have you been diagnosed with a sexually transmitted infection in the last 3 months?
   Yes ☐
   No ☐

10. Have you used an emergency form of contraception in the last 3 months ("morning after" pill or IUD)? Yes ☐
    No ☐

11. Have you had a condom failure in the last three months (i.e. condom has slipped off/ripped)?
    Yes ☐
    No ☐

Part B

The following are 16 statements about using a condom, some of which are correct, and some of which are incorrect.

Circle the eight correct statements.

1. Use a latex condom

2. Tear along one side of the foil, being sure not to rip the condom inside

3. Put the condom on anytime before you ejaculate

4. Put the condom on when the penis is erected, before there is any contact between the penis and the partner's body

5. Unroll the condom before placing on the penis

6. Withdraw the penis while it is still erected by holding the condom firmly in place. Remove the condom

7. Unroll the condom to approximately three quarters of the way down the penis

8. Apply a water-based lubricant (i.e. K.Y. Jelly)

9. Squeeze the closed end of the condom between your forefinger and thumb and place the condom over the erected penis

10. Wrap the used condom back in the foil to save for the next time

11. Unroll the condom to the base (hair) of the penis

12. Apply an oil-based lubricant (i.e., oil, Vaseline, lotion)

13. Withdraw the penis after it is no longer erected by holding the condom firmly in place. Remove the condom

14. Put the condom on before the penis is erected, before there is any contact between the penis and the partner's body

15. Unroll the closed end of the condom keeping two inches between the end of the condom and the tip of the penis

16. Dispose of the used condoms

Part C

For the following statements please circle the number that most closely describes your opinion

1. I can say no to sex with a new partner if we don't have a condom even if I want to have a relationship.

1	2	3	4	5
Not at all sure				Completely sure I can do

2. I can avoid situations that can lead to unsafe sex when I don't have a condom.

1	2	3	4	5
Not at all sure				Completely sure I can do

3. I can say no to sex if my partner and I don't have a condom even if we have not used one in the past.

1	2	3	4	5
Not at all sure				Completely sure I can do

4. I can avoid getting high or drunk when I'm going to have sex.

1	2	3	4	5
Not at all sure				Completely sure I can do

5. I can talk to a partner about using a condom before I become too aroused.

1	2	3	4	5
Not at all sure				Completely sure I can do

6. I can always use a condom even if I'm buying or selling sex or trading sex for drugs.

1	2	3	4	5
Not at all sure sure				Completely sure I can do

7. I can talk to every partner about the importance of using condoms even those I've had sex with before.

1	2	3	4	5
Not at all sure sure				Completely sure I can do

8. I can always take a condom with me when I go out, just in case I need it.

1	2	3	4	5
Not at all sure sure				Completely sure I can do

9. I can talk to every new partner about the importance of using condoms.

1	2	3	4	5
Not at all sure sure				Completely sure I can do

10. I can find another pleasurable activity (such as mutual masturbation) when a condom isn't available.

1	2	3	4	5
Not at all sure sure				Completely sure I can do

11. I can stop before sex to use a condom, even if I am very sexually aroused.

1	2	3	4	5
Not at all sure sure				Completely sure I can do

12. I can always keep a supply of condoms at home.

1	2	3	4	5
Not at all sure sure				Completely sure I can do

13. I can pull out (or have my partner pull out) while still erect after ejaculating (cumming) when having sex with a condom.

1	2	3	4	5
Not at all sure sure				Completely sure I can do

14. I can use a condom with a partner even if the room is dark.

1	2	3	4	5
Not at all sure sure				Completely sure I can do

15. I can use a condom without fumbling.

1	2	3	4	5
Not at all sure sure				Completely sure I can do

16. I can be the one to put the condom on, even if I'm with a new sexual partner and am nervous.

1	2	3	4	5
Not at all sure sure				Completely sure I can do

17. I can put a condom on (myself/ my partner) so that it will not slip or break.

1	2	3	4	5
Not at all sure sure				Completely sure I can do

18. I can get every partner who I've ever had sex with before to use a condom even if they do not want to.

1	2	3	4	5
Not at all sure sure				Completely sure I can do

19. I can get every partner to use a condom even if we haven't used them in the past.

1	2	3	4	5
Not at all sure sure				Completely sure I can do

20. I can get every partner to use a condom even if they don't want to.

1	2	3	4	5
Not at all sure sure				Completely sure I can do

21. I can make sex fun using a condom with a new partner.

1	2	3	4	5
Not at all sure sure				Completely sure I can do

22. I can make sex fun using a condom with a partner, even if we haven't used them in the past.

1	2	3	4	5
Not at all sure sure				Completely sure I can do

23. I can put a condom on (myself/ my partner) and enjoy the experience.

1	2	3	4	5
Not at all sure sure				Completely sure I can do

24. I can be the one to put the condom on without ruining the mood.

1	2	3	4	5
Not at all sure				Completely sure I can do

25. I can get a new partner to use a condom even if I'm drunk or high.

1	2	3	4	5
Not at all sure				Completely sure I can do

26. I can get a partner who I haven't used condoms with before to use one, even if I'm drunk or high.

1	2	3	4	5
Not at all sure				Completely sure I can do

Part D

For the following questions please circle the number that most closely describes your answer

1. How often would you use condoms with a casual partner

1	2	3	4	5
Not Often				Most Often

2. How likely is it that you would use condoms every time with a casual partner

1	2	3	4	5
Not Likely				Most Likely

3. How sure are you that you would use condoms every time with a casual partner

1	2	3	4	5
Not Sure				Most Sure

4. How likely is it that you would not use condoms in the next 6 months with a casual partner

1	2	3	4	5
Not Likely				Most Likely

5. How often would you use condoms with a main partner

1	2	3	4	5
Not Often				Most Often

6. How likely is it that you would use condoms every time with a main partner

1	2	3	4	5
Not Likely				Most Likely

7. How sure are you that you would use condoms every time with a main partner

1	2	3	4	5
Not Sure				Most Sure

8. How likely is it that you would not use condoms in the next 6 months with a main partner

1	2	3	4	5
Not Likely				Most Likely

Part E

For each of the following questions please tick ☑the box that most closely describes your alcohol use

Questions	0	1	2	3	4	
1. How often do you have a drink containing alcohol?	Never	Monthly or less	2-4 times a month	2-3 times a week	4 or more times a week	
2. How many drinks containing alcohol do you have on a typical day when you are drinking?	1 or 2	3 or 4	5 or 6	7 to 9	10 or more	
3. How often do you have six or more drinks on one occasion?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
4. How often during the last year have you found that you were not able to stop drinking once you had started?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
5. How often during the last year have you failed to do what was normally expected of you because of drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
6. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
7. How often during the last year have you had a feeling of guilt or remorse after drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
8. How often during the last year have you been unable to remember what happened the night before because of your drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
9. Have you or someone else been injured because of your drinking?	No		Yes, but not in the last year		Yes, during the last year	
10. Has a relative, friend, doctor, or other health care worker been concerned about your drinking or suggested you cut down?	No		Yes, but not in the last year		Yes, during the last year	

Thank you for completing this questionnaire

Appendix 7: Session Evaluation Form

Session Evaluation

For the following statements please circle the number that most closely describes your opinion

1. This session was enjoyable for me

1	2	3	4	5
Yes				No

2. I found this session interesting

1	2	3	4	5
Yes				No

3. Completing this session with others was beneficial

1	2	3	4	5
Yes				No

4. I have learnt things today which are relevant to me

1	2	3	4	5
Yes				No

5. I have learnt things today that may benefit my health

1	2	3	4	5
Yes				No

6. I would recommend this session to others

1	2	3	4	5
Yes				No

Appendix 8: Participant Information Sheet

Information Sheet

You are being invited to take part in a research study that is being organised by a UWE doctoral student. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

Study Title

Evaluation of a skill-based condom intervention in an alcohol-using student population: a pilot study.

What is the purpose of the study?

This pilot study aims to find out whether an intervention designed to promote condom use is effective in students that drink alcohol.

Am I eligible to take part?

This study is open to female UWE students who identify as being sexually active and who drink six or more standard drinks in one occasion once a month or more often. If you are pregnant you are not eligible to take part in this study. It is expected that 24 participants will take part in this study.

Do I have to take part?

Your participation in this study is entirely voluntary. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your assessment marks or any aspect of your education.

If you choose to take part, this study will contribute to UWE research credits.

What will happen to me if I take part and what do I have to do?

If you choose to take part you will be required to attend an intervention session at UWE lasting for approximately 4 hours. The session will involve some form of health education. You will be asked to complete a questionnaire prior to the session starting and immediately after it finishes. You will be asked to complete a practical assessment regarding how to put a condom on an anatomical model before the session and immediately after the session finishes. You will also be asked to fill in a questionnaire 3 months after the intervention session. This will be posted to you and returned anonymously.

Will my participation in this study be kept confidential?

All information which is collected about you during the course of the study will be kept strictly confidential. Questionnaires will be collected anonymously and neither the researcher nor any assistants helping with the study will be able to identify you from your questionnaire. Any printed information with your details on it such as your consent form will not leave UWE and will be kept in a locked drawer. Only the researcher and the researchers' supervisor will have access to printed records of your details for the purposes of posting a questionnaire to you after the study has finished.

What are the possible disadvantages and risks of taking part?

The questionnaire will include asking you about elements of your condom and alcohol use. Your responses will not be shared with anyone. A member of the research team will be available should answering of the questions raise any issues that you wish to obtain more information about.

What are the possible benefits of taking part?

Taking part in the study may provide you with useful health information.

What if something goes wrong?

If there is any element of the study that you are not happy with then please contact the research supervisor (details at the end of this sheet).

What will happen to the results of the research study?

The results from this study will contribute to a doctoral qualification. You would not be able to be identified as having taken part in the study from either the doctoral write-up of the study or any publications that arise from it. A sample copy of the findings will be available to you if you choose.

Researcher Details	**Supervisor Details**
Miss Zoe Hurrell C/o Dr. Rachel Gillibrand UWE Faculty of Applied Sciences Department of Psychology Frenchay Campus Bristol BS16 1QY zoe2.hurrell@live.uwe.ac.uk Tel: 0117 32 83385	Dr. Rachel Gillibrand UWE Faculty of Applied Sciences Department of Psychology Frenchay Campus Bristol BS16 1QY rachel.gillibrand@uwe.ac.uk Tel:0117 32 83385

Thank you for taking the time to read the information above. If you are interested in taking part in the study please do not hesitate to contact me.

Many Thanks

Zoe Hurrell

Appendix 9: Consent Form

Consent Form

Please read the following list of statements and tick ☑ all those that you agree with:

I have read and understood the nature of the research project as outlined in the information sheet. ☐

I feel as though I have received enough information about the study. ☐

I feel as though I have had sufficient time to come to my decision. ☐

I understand that I am free to withdraw from the study at anytime without reason. ☐

I agree to participate in the study. ☐

Signature:.....

Print name: .....

Date: .....

Appendix 10: Debrief Sheet

Debriefing Form

If you have any queries about the study or have any further questions please do not hesitate to contact me on the details provided below.

I'd like to take this opportunity to say thank you for your contribution to the current study. A sample copy of the findings will be available to you if you choose.

Contact Details
Miss Zoe Hurrell C/O Dr. Rachel Gillibrand
UWE Faculty of Applied Sciences
Department of Psychology
Frenchay Campus
Bristol
BS16 1QY
Tel: 0117 32 83385
E-mail: zoe2.hurrell@live.uwe.ac.uk or rachel.gillibrand@uwe.ac.uk

Please find below some useful condom/contraception and alcohol advice links that you may wish to visit:

- NHS advice for students including sexual health and alcohol:
  http://www.nhs.uk/Livewell/studenthealth/Pages/Studenthealthhome.aspx
- Family planning and sexual health advice for all ages
  http://www.fpa.org.uk/Homepage
- UWE University Health Centre
  http://www.uwe.ac.uk/advice/healthcentre/
- Bristol Sexual Health Centre
  http://www.uhbristol.nhs.uk/sexual-health
- Drink Aware for advice on alcohol including student specific advice
  http://www.drinkaware.co.uk/
- Bristol Rape Crisis Helpline
  http://www.bristolrapecrisis.org.uk/helpline.php
- Brook for sexual health advice for those under 25 years of age
  http://www.brook.org.uk/professionals/home
- IPPF – a global sexual health provider including advice on condom negotiation
  http://www.ippf.org/en/
- Alcoholics Anonymous for help and support if you feel alcohol is causing you problems
  http://www.alcoholics-anonymous.org.uk/
- British Heart Foundation
  http://www.bhf.org.uk

Appendix 11: Introduction and Session Conclusion/Debrief Scripts

Introduction/Overview/Ground Rules

Welcome everyone. Thanks for taking time out to take part in this study. My name is Zoe and I am conducting this piece of research. Today's session is mainly going to be delivered by …….. and …….. is also assisting us today. We will be here today for approximately ……. hours.

There are a few house-keeping points to go over;

- Toilets are…..,
- Fire exits are…. (we are not expecting a fire alarm to go off so if one does we will take it seriously)
- Please turn off mobile phones/put to silent. If you need to make/receive urgent calls please let me know.
- Feel free to drink water during the sessions. We will stop for a break approximately half way in to the session.
- If you need to leave the room for any reason (toilet etc) please let me know.

As you know, this research is exploring whether an intervention designed to encourage condom use is effective in students that binge-drink. **Today will involve watching some health promotional material, group discussion and possibly some practical exercises.** Before we start this session today it would be really helpful if you could fill in a questionnaire. You will also be required to perform a practical exercise of putting on a condom on to an anatomical model. This will be done in a separate room. After the session you will be asked to complete another questionnaire and do a second condom exercise.

…….. will give you a name badge (feel free to call yourself whatever you please) – this is just to facilitate the social element of this session. Your questionnaire responses will remain entirely confidential. Your consent form will be detached from your questionnaire when you hand it over and they will be stored securely and separately.

We hope that today will be educational AND fun! If anyone requires more information or support arising from anything we discuss in this session please let me know. You will be provided with a debriefing form at the end of today's session.

I would like to suggest a few group rules for today's session and if anyone would like to add anything then shout out. ..

- Only one person talking at a time
- You are NOT required to divulge any personal information about yourself to the group! If you would like to contribute to any discussion then feel free to talk in the third person. You are also not required to share any responses from your questionnaire!
- You are free to contribute as much or as little to any of the group discussions.

Session Conclusion/Debrief

To the control group:

"You are part of a larger study looking at the effectiveness of a condom intervention. This group was the control group of this study which means you did not receive any condom advice.

To all groups:

"If you would like any information please help yourself to any of the leaflets" (leaflets to be displayed to all groups; Ask Brook About STIs, Ask Brook About Condoms, Ask Brook About Sex and Alcohol, BHF information).

"Please read the Debriefing Form carefully. If you require any further information please contact one of the organizations listed or speak to me after the session ends. Before you leave we will need to get a postal address for you so that a questionnaire can be posted to you in 3 months time. You will not receive research credits for participation until a follow-up questionnaire has been returned. If you would like to receive a sample copy of the findings of this study, please let me know before you leave. Thank you again for your participation in this study"

Appendix 12: Kolmogorov-Smirnov Test

Tests of Normality

question		group	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
			Statistic	df	Sig.	Statistic	df	Sig.
1	sex	Control	.211	7	.200*	.953	7	.759
		Info-onl	.274	9	.050	.707	9	.002
		Skills	.328	8	.011	.851	8	.098
	sexcon	Control	.339	7	.015	.781	7	.027
		Info-onl	.428	9	.000	.510	9	.000
		Skills	.259	8	.122	.866	8	.139
	sexdrunk	Control	.314	7	.035	.770	7	.020
		Info-onl	.163	9	.200*	.909	9	.308
		Skills	.253	8	.139	.778	8	.017
	sexcondr	Control	.342	7	.013	.602	7	.000
		Info-onl	.439	9	.000	.505	9	.000
		Skills	.367	8	.002	.682	8	.001
3	sex	Control	.192	7	.200*	.919	7	.464
		Info-onl	.384	9	.000	.531	9	.000
		Skills	.269	8	.092	.844	8	.082
	sexcon	Control	.334	7	.018	.777	7	.024
		Info-onl	.403	9	.000	.472	9	.000
		Skills	.170	8	.200*	.926	8	.482
	sexdrunk	Control	.321	7	.028	.853	7	.131
		Info-onl	.451	9	.000	.454	9	.000
		Skills	.311	8	.022	.739	8	.006
	sexcondr	Control	.414	7	.001	.630	7	.001
		Info-onl	.485	9	.000	.423	9	.000
		Skills	.336	8	.008	.715	8	.003

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

Tests of Normality[c]

question		group	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
			Statistic	df	Sig.	Statistic	df	Sig.
1	mocustot	Control	.172	7	.200*	.967	7	.873
		Info-onl	.289	9	.029	.765	9	.008
		Skills	.284	8	.057	.906	8	.324
2	mocustot	Control	.249	7	.200*	.889	7	.271
		Info-onl	.356	9	.002	.655	9	.000
		Skills	.263	8	.109	.827	8	.056

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

Tests of Normality

question		group	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
			Statistic	df	Sig.	Statistic	df	Sig.
1	cuscscor	Control	.241	7	.200*	.937	7	.609
		Info-onl	.284	9	.035	.863	9	.102
		Skills	.250	8	.150	.849	8	.093
2	cuscscor	Control	.421	7	.000	.646	7	.001
		Info-onl	.414	9	.000	.617	9	.000
		Skills	.300	8	.033	.798	8	.027
3	cuscscor	Control	.264	7	.149	.887	7	.262
		Info-onl	.278	9	.044	.853	9	.081
		Skills	.371	8	.002	.724	8	.004

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

Appendix 13: Kruskall-Wallis Test

Questionnaire time-point 1: Sex without a condom/Sex whilst drunk without a condom

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of sexcon is the same across categories of group.	Independent-Samples Kruskal-Wallis Test	.300	Retain the null hypothesis.
2	The distribution of sexcondr is the same across categories of group.	Independent-Samples Kruskal-Wallis Test	.077	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

Questionnaire time-point 3: Sex without a condom/Sex whilst drunk without a condom

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of sexcon is the same across categories of group.	Independent-Samples Kruskal-Wallis Test	.215	Retain the null hypothesis.
2	The distribution of sexcondr is the same across categories of group.	Independent-Samples Kruskal-Wallis Test	.252	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

Questionnaire time-point 1: CUSC/CUSES/Intentions/MOCUS

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of cuscscor is the same across categories of group.	Independent-Samples Kruskal-Wallis Test	.352	Retain the null hypothesis.
2	The distribution of cusestotal is the same across categories of group.	Independent-Samples Kruskal-Wallis Test	.608	Retain the null hypothesis.
3	The distribution of intentiontotal is the same across categories of group.	Independent-Samples Kruskal-Wallis Test	.358	Retain the null hypothesis.
4	The distribution of mocustot is the same across categories of group.	Independent-Samples Kruskal-Wallis Test	.037	Reject the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

Questionnaire time-point 2: CUSC/CUSES/Intentions/MOCUS

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of cuscscor is the same across categories of group.	Independent-Samples Kruskal-Wallis Test	.074	Retain the null hypothesis.
2	The distribution of cusestotal is the same across categories of group.	Independent-Samples Kruskal-Wallis Test	.243	Retain the null hypothesis.
3	The distribution of intentiontotal is the same across categories of group.	Independent-Samples Kruskal-Wallis Test	.379	Retain the null hypothesis.
4	The distribution of mocustot is the same across categories of group.	Independent-Samples Kruskal-Wallis Test	.001	Reject the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

Questionnaire time-point 3: CUSC/CUSES/Intentions/MOCUS

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of cuscscor is the same across categories of group.	Independent-Samples Kruskal-Wallis Test	.127	Retain the null hypothesis.
2	The distribution of cusestotal is the same across categories of group.	Independent-Samples Kruskal-Wallis Test	.405	Retain the null hypothesis.
3	The distribution of intentiontotal is the same across categories of group.	Independent-Samples Kruskal-Wallis Test	.757	Retain the null hypothesis.
4	The distribution of mocustot is the same across categories of group.	Independent-Samples Kruskal-Wallis Test	.	Unable to compute.

Asymptotic significances are displayed. The significance level is .05.

Part 4: Reflective Chapter

This chapter provides a reflection on my development as a health psychologist throughout the DHealth programme. How the core competencies of the DHealth portfolio have been fulfilled by my employment experiences is covered as well as how conducting my research project has been influential in my development as a psychologist. A brief examination of my overall professional and personal development concludes this reflective chapter with consideration given to plans for the future.

The contribution of employment in attaining DHealth competencies

During my years of study at UWE, I have developed skills in the following core competencies that comprise my DHealth portfolio, which has been aided by my employment as a trainee health psychologist within the Health Psychology Department (HPD) at Gloucestershire Hospitals NHS Foundation Trust (GHNHSFT), which started approximately nine months prior to starting the DHealth programme.

1. Teaching and Training
2. Consultancy
3. Interventions
4. Professional Skills
5. Research (including a Systematic Review)

Fulfilment of these competencies evolved through the integration of taught practice delivered by UWE with my employment at GHNHSFT. I was employed by the Trust for just over four years in total during which time I was primarily involved in the cardiac rehabilitation (CR) team and the community health research team, which undertook various research contracts. For the purposes of fulfilling the requirements of the DHealth programme, my work within the CR team provided me with the most valuable experience and developed my expertise, particularly in the areas of Teaching and Training, Interventions and Professional Skills.

The core CR team comprised three disciplines: nursing, physiotherapists/exercise specialists and psychology. As one of the health psychology trainees I would work alongside a member of the nursing and exercise team to deliver a multidisciplinary service which consisted of community group programmes aimed at managing coronary heart disease (CHD) for those who had experienced angina, heart attack, stenting or coronary artery bypass surgery. Our group programmes involved delivering sessions combining all three disciplines to patient groups in the community. As one of the team psychology trainees I would deliver talks covering the psychological impact of a cardiac event, goal-setting and pacing, stress, making lifestyle behavioural changes and making the most of one's recovery in terms of resumption of activities. If patients required more tailored advice, I would speak to them on a one-to-one basis at the end of sessions or during breaks. In addition to group programmes I also started carrying out assessments about halfway through my employment at GHNHSFT with CHD in-patients on the cardiology wards who had suffered an acute cardiac event, helping them to identify their risk factors for CHD, possible avenues for future behavioural lifestyle change and recruitment to one of the community group programmes.

Both delivering group sessions and conducting in-patient assessments involved a steep learning curve to begin with. The thought of speaking in a group setting initially was particularly daunting; however, overall, it is the facet of my job which I feel I excelled in more than any other and the area I found most rewarding. Hence, although the Teaching and Training competency at first presented a significant worry to me it now comprises the element I am most proud of. My proficiency in teaching patient groups has led to greater confidence in teaching different groups such as BSc student nurses and MSc health psychology students in topics such as CR, CHD, stress and latterly sexual health.

In terms of fulfilling the Interventions competency, I was able to use my experience of working with CHD patients within both the community group programmes and in-patient assessments as they contributed to a good knowledge of intervention design, management and evaluation. Thus, my CR work provided a sound basis for writing up one of my Interventions pieces submitted within my portfolio as I was able to use a plan for behavioural change that I devised with one of the CR patients.

In addition, my employment role generally, although most particularly within CR, contributed greatly to the development of my Professional Skills competency. During my time within the CR team, my confidence grew in many spheres such as dealing with patient suicidal ideation, managing patient group dynamics, working on more tailored behavioural plans for patients with more specialised goals and signposting to additional services as part of a holistic approach to care. My development as a psychologist evolved over the course of my employment and was supported by regular supervision with my line manager as well as the DHealth programme, most notably by the requirements of the Professional Skills competency

for which I kept a detailed log of the activities I undertook and the challenges that arose, which served as a useful tool for reflection.

The contribution of conducting research in developing as a psychologist

My tasks within the community health research team at GHNHSFT tended to be isolated cogs in a much larger research machine, thus I did not have the benefit of seeing an entire research project through from beginning to end or possess complete ownership of any phase. Rather, I contributed to various data management procedures as part of a wider team. For this reason, amongst many others, I decided to conduct my doctoral research in an area completely separate from my employment. Sexual health has always been an academic field of research that I have had an interest in, from my days as a BSc psychology student to my previous employment role as a genitourinary technician (some 10 years ago) to my more recent MSc health psychology studies. I therefore set about conducting a systematic review (SR) of the evidence looking at the effectiveness of condom interventions in those who binge-drink and used this as a basis for my doctoral research. This involved running a feasibility study exploring the effectiveness of a skills-based condom intervention in students who use alcohol. There were consequences to this decision; on a positive note, my portfolio would display greater diversity than if all my competencies were based in CR. In addition, the research involved designing the intervention and collaborating with outside parties, thus I was also able to write up this experience for my Interventions and Consultancy competencies. Less positively, however, was the fact that this research had to be undertaken entirely within my own time as it did not constitute any of my employment obligations. This

was a heavy burden and for most of my training period I struggled with attaining a good balance between my work, studies and personal life.

Having complete ownership over my research project from conceptualising the study design, carrying out the research sessions and evaluating it has provided valuable insights into the pragmatics of conducting research. I faced many challenges getting the project up and running in terms of recruitment and the scheduling of sessions. Most notably, my eligibility criteria for taking part in the study initially required participants to not be using alternative forms of contraception; however, this resulted in too few participants signing up to take part. The time pressure involved in this study (having to complete before research credits needed to be submitted) rendered this approach unworkable, and so I took the decision to omit this particular criterion in order to encourage more research participation. This did indeed occur; however, as a result, the usefulness of my research was consequently compromised. I also faced difficulties in terms of the length of follow-up period my study could accommodate. As I had a fixed end date (specified by the research credit deadline), the difficulties in recruiting led to an ever-shortening follow-up period. I did consider the option of awarding research credits before follow-up data was collected, although this ran the risk of diminished follow-up data being returned. I therefore chose a reduced follow-up period above the possibility of zero follow-up data. Such choices made this project quite pressured at times. That being said, on balance I feel as though I made the most considered and logical choices. I also experienced difficulties in terms of how I was able to conceptualise and define this research, particularly in terms of the language used to communicate ideas such as “piloting” versus “feasibility” and “study” versus “intervention”. Overall, these challenges have strengthened my experiences and will benefit future research opportunities.

Professional and personal development – past, present and future

Over the course of my trainee position at GHNHSFT, I undertook compulsory training (cognitive behavioural therapy) as well as voluntary training (in motivational interviewing) and I found both to be of great use in carrying out my role. These training opportunities, alongside my professional development in the role of trainee health psychologist garnered through the acquisition of experience and regular supervision with my line manager, have engendered a sense of confidence in many spheres. However, I can still identify areas of improvement. For example, whilst my key responsibilities centred on delivering patient groups and conducting in-patient assessments, there was no scope for more structured, one-to-one work, and this very much felt like a wasted opportunity. To this end, I feel that I could have developed more professionally in terms of delivering tailored behavioural change advice had the opportunity arisen.

This latter point is pertinent currently as I have recently taken on the role of sexual health improvement specialist working for Sirona Care and Health (a Social Enterprise). Some of this role involves direct contact with young people whilst undertaking Chlamydia Outreach events, and thus honed and succinct behavioural change advice at these events would be most beneficial. I am currently engaged in a hefty training programme to meet the demands of this new role, and as part of this I aim to deepen my understanding of approaches which will be of benefit in delivering opportunistic sexual health advice. My current role carries a great deal of freedom in terms of how I contribute to the Commissioner-led targets in reducing teenage pregnancy and reducing sexually transmitted infections in the local area. Whilst some of the role centres on direct work with young people, I am also required to build links with many other professionals and agencies in order to provide a holistic approach to

local sexual health provision and am therefore working on a plan to address issues such as substance misuse, accessing vulnerable populations and bigger-picture strategy-level work. As I am in the early stages of this role, I am currently assessing where my academic approach and training can contribute to my post. I feel the potential for how my DHealth training will be of use will centre on consolidating an evidence base of current practice as well as theoretically underpinned future health campaigns and interventions.

Looking forwards to the future longer term, I really hope to be able to fly the flag for health psychology in my workplace. I am in the curious position of being in a team of employees who are all "doing" health psychology (such as smoking cessation, healthy eating, sexual health, etc.), although there appear to be no other health psychologists in the team and a general unawareness of the field. The opportunity to incorporate some core health psychology approaches and make use of the competencies I have developed on the DHealth programme is therefore awash with possibility.

I feel I have developed as much personally as professionally since commencing the DHealth programme. Juggling the demands of the DHealth programme alongside a job and a busy family life has forced me to organise myself in a way which I had never had to consider before. Although this has been a challenge, I feel it has brought about a more healthy approach to my career development and fulfilment. My training period on the DHealth programme has seen me evolve from a rather green MSc graduate to a more confident and assured professional working in my preferred area of health. The combination of my employment experience, work and academic supervision, DHealth training and peers has encouraged me on my way to chartered status and I am sure will remain fundamental in my future development as a health psychologist.