

Accepted Manuscript.

Article accepted for publication in Applied Psychology: Health and Well-Being, 09/09/2018.

Self-control, plan quality and digital delivery of action planning for condom and contraceptive pill use of 14-24 year olds: Findings from a clinic-based online pilot randomised controlled trial.

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Abstract

Background Inconsistent use of the contraceptive pill and condoms contributes significantly to poor sexual health outcomes for young people. There is evidence that action planning interventions may improve pill and condom use, but this approach is not systematically used in sexual healthcare. This study is the first to assess acceptability and feasibility of evaluating a digital intervention to support action plan formation for three sexual health behaviours with clinic attendees. It also considered the role of trait self-control and whether the intervention supported production of quality plans. **Methods** 88 integrated sexual health clinic attendees aged 14-24 years (m=20.27 years) were recruited to a pilot randomised controlled trial (RCT). Of these, 67 also completed three-month follow-up. Measures included self-reported contraceptive or condom ‘mishaps’, theory of planned behaviour variables and a measure of self-control. **Results** Descriptive analyses supported study acceptability and feasibility. The intervention supported pill *and* condom users to produce quality plans, though potential improvements were identified. Bivariate correlations suggested high levels of trait self-control may negatively influence plan quality. Data suggest the intervention may reduce pill or condom ‘mishaps’. **Conclusions** A future full RCT is likely feasible and brief digital action planning interventions may usefully be incorporated within sexual healthcare.

Key words: Action planning, self-control, contraceptive pill, condom use, eHealth, online

Abbreviations:

MSM	Men who have sex with men
NHS	National Health Service
NIHR	National Institute for Health Research
PHE	Public Health England
RCT	Randomised Controlled Trial
STI	Sexually Transmitted Infection
WHO	World Health Organisation

Introduction

Poor sexual health outcomes such as diagnosis of sexually transmitted infections (STI), and unintended pregnancy are a global public health burden. Each year there are for example, 357 million new diagnoses of chlamydia, gonorrhoea, syphilis and trichomoniasis (WHO, 2016) and the consequences can go beyond the infections themselves resulting in serious negative sequelae such as infertility and stillbirth via mother-to-child transmission (WHO, 2016). Similarly, unintended pregnancy and/or unwanted pregnancy continues to burden women worldwide. Despite a reduction in abortion rates globally in the last 30 years, 2.7% of women in the developed world and 3.7% of women in the developing world had an abortion between 2010 and 2014 (Sedgh, Bearak, Singh, et al., 2016). Continued efforts are required to improve these outcomes.

In the UK, sexual health remains a public health priority, with rates of chlamydia detection and numbers of people presenting late for HIV diagnosis featuring in the most recent Public Health Outcomes Framework (DH, 2016). Although UK rates of teenage pregnancy have halved in recent years and there has been a decline in new diagnoses of some STIs, there have also been sharp increases in STI rates for some groups (e.g. Men who have sex with men (MSM)) and young people aged 15 to 24 years continue to account for the majority of new STI diagnoses (PHE, 2017). Whilst a variety of contraceptive methods are freely available in the UK, young people tend to favour the two most behaviourally intensive methods; the contraceptive pill and condoms (Bayley, Baines & Brown, 2017). In addition, condoms (including the female condom), remain the only widely available and affordable method of protecting against STI transmission during sex (Colquit & Martin, 2015). Because condoms must be used correctly throughout every occasion of penetrative sex and the pill must be taken every day, the propensity for forgetting to take the pill or engaging in condom-less sex or inconsistent and incorrect condom use is widespread and contributes greatly to the sexual health problems outlined above.

Young people typically express having strong intentions to use condoms and/or the contraceptive pill consistently (Brown, Arden & Hurst, 2011), but both self-reports of consistent use (Brown, Abraham, Joshi & Wallace, 2011; Gebhart, Keyper & Dusseldorp, 2006), and objective data outlined above about unintended pregnancy (Sedgh et al., 2016) and diagnoses of STI (WHO, 2016) suggest those intentions do not translate fully to consistent action. Such outcomes represent consistent findings in the literature relating to the application of largely reasoned, motivational theoretical explanations of behaviour, such as the Theory of Planned Behaviour (TPB; Ajzen, 1991). The TPB has consistently been found

to explain a significant proportion of the variation in condom use intention (e.g. 24% in recent analysis by Andrew, Mullan, de Wit et al., 2016) and behaviour (e.g. 12.4% in Andrew, Mullan, de Wit et al., 2016) but has also been criticised (amongst other things) for the relatively large proportion of variance in behaviour that remains unexplained by a measure of intention (and perceived behavioural control) (e.g. Sniehotta, Preece & Araújo-Soares, 2014). This ‘intention-behaviour gap’ is common across health-related behaviours (Prestwich, Sheeran, Webb & Gollwitzer, 2015). An intervention approach that has been found to consistently help to improve behavioural outcomes when motivation is already strong is supporting people to form detailed action plans (Sniehotta, Schwarzer, Scholz & Schüz, 2005) about how, when and where they will perform the health behaviour. Action plans have also been referred to interchangeably by some (see Hagger & Luszczynska, 2014) as ‘if-then’ plans or implementation intentions (Prestwich et al., 2015). Hagger & Luszczynska (2014) identify some distinct differences however in their assessment of the derivation and operationalisation of these approaches. Action planning has no single derivation and appears in a range of theoretical models including the Health Action Process Approach (HAPA; Schwarzer & Luszczynska, 2008), and the Integrated-Change Model (I-Change Model; de Vries, Mesters, van de Steeg, & Honing, 2005). Its operationalisation typically includes a greater focus on *how* the behaviour will be enacted and may be paired with ‘coping planning’ (planning for how one will cope with temptations and challenges during an attempt to change behaviour). Implementation intentions are principally derived from the work of Peter Gollwitzer and colleagues (Gollwitzer, 1999; Gollwitzer & Sheeran, 2006) relating to the ‘Rubicon’ model (Heckhausen & Gollwitzer, 1987). They typically employ a greater focus on linking a very specific behaviour to a specific unconditional environmental cue (Hagger & Luszczynska, 2014), although both include creating a link between an intended goal-directed behaviour and an environmental cue. In practice, field-based applied research may require a greater flexibility in identifying behavioural cues, than the strict ‘if-then’ format proposed by Gollwitzer (1999) and therefore in the present study we refer to action planning when describing our own intervention.

Extant research applying implementation intentions to contraceptive pill use amongst female attendees at a family planning clinic identified a significant decrease in access to emergency contraceptives, pregnancy testing and pregnancy termination in intervention participants compared with controls (Martin, Sheeran, Slade et al., 2009, 2011). Similarly, De Vet and colleagues (2011; unpublished manuscript) showed that amongst women participating in a text-message based implementation intention intervention targeting both

condom use and condom use preparation behaviours (i.e. buying, carrying, mentioning condoms), forming precise and complete (i.e. high quality) plans to access, carry and mention condoms led to increases in these preparatory behaviours. Forming high quality plans for actual condom use was harder for participants due to the often unplanned nature of sexual encounters (De Vet et al., 2011). Arguably however, there is merit in supporting young people to make action plans relating to daily contraceptive pill use and preparatory condom use behaviours, and the quality of those plans is likely to be important.

Recent research exploring action plan quality has considered a range of features including; the specificity of contextual cues (when/where/with who) and behavioural responses (then/what/how) (e.g. Fleig, Gardner, Keller et al., 2017; Keller, Fleig, Hohl et al., 2017); instrumentality (i.e. how goal directed the plan is) (e.g. De Vet et al., 2011; Fleig et al., 2017; Reinwand, Crutzen, Storm et al., 2016); and viability (i.e. how realistic the plan is) (e.g. Fleig et al., 2017). It is generally expected that greater levels of each of these will be related to greater levels of plan enactment and achievement of the target behaviour.

Reinwand et al. (2016) found that guiding those motivated enough to engage in action planning through the process in a computer-based intervention led to almost 100% of plans to be highly instrumental and a majority to be highly specific. In relation to plan enactment, Keller et al. (2017) found that regarding contextual cues, identifying a routine to link the planned behaviour to, was more effective than identifying a specific time. Similarly, Fleig et al (2017) identified that the specificity of the contextual cue (when) was important for plan enactment, as was instrumentality, but lower levels of specificity relating to behavioural response were more strongly related to plan enactment (Fleig et al. 2017). In the present study, similar to Reinwand et al. (2016) we aimed to support the construction of highly instrumental plans for participants, and to support the specificity of contextual cues linked to existing routines (cf. Fleig et al., 2017) which should also support viability. Behavioural responses for *taking the pill* and the preparatory behaviour of *buying/accessing condoms* are limited anyway in relation to flexibility of response but we aimed to support flexibility with regards ways to 'mention' condoms to a partner.

Research exploring the broader potential of implementation intention intervention strategies has been able to establish that applying this technique does not require participants to draw on self-regulatory resources (i.e. application of conscious and effortful mental capacity; Webb & Sheeran, 2003). This is likely to be important for health behaviours that typically require high levels of self-control, such as condom use. In a lab-based study, Webb & Sheeran (2003) found that forming implementation intentions helped people to overcome

depletion of their self-regulatory resources (i.e. low state self-control; brought about by engagement in a balance-and-maths task) and perform as well as non-resource-depleted comparators at a stroop task. This finding has potential and currently unexplored real-world implications for this type of intervention, relating to those with naturally lower versus higher capacity for applying self-regulatory resources (i.e. low trait self-control). For example, it may be that those with high trait self-control form higher quality plans. Understanding any relevant effect of this capacity on action planning with regards condom and contraceptive pill use may be useful for tailoring application within sexual health improvement programmes in the future.

Previous research with sexual health professionals has illustrated that, with contraceptive pill use at least, staff may informally apply implementation intention and/or action planning approaches in their health communications with young women (Brown, Abraham, Joshi & Wallace, 2012). Delivering this type of intervention in the context of sexual health clinics is likely to reach young people when they are most receptive, since their attendance at the clinic is likely to indicate acknowledgement of a sexual health related need and a moment of relatively higher motivation to engage in safer sex behaviours in the future. There has been no attempt as yet however, to more systematically embed detailed action planning interventions into sexual health care. Given that sexual health professionals may lack the time and skills to deliver this type of intervention, and a growing interest in the potential for digital health promotion tools, we devised an interactive digital tool to support contraceptive pill and condom use action planning which has been tested for usability and acceptability to sexual health professionals (Brown et al., 2012). Additional benefits of digital interventions include fidelity to intervention delivery. Extant literature has illustrated issues with use of digital and online interventions in NHS and sexual health clinic settings (e.g. Bailey, Webster, Griffin et al., 2016). In order to understand the feasibility of using this intervention within a clinic setting and to test whether a randomised controlled trial design would work we conducted a pilot randomised controlled trial. As well as assessing self-reported 'mishaps' with the pill or condoms, standard psychological determinants of contraceptive pill and condom use based on the TPB, and an assessment of plan quality, we employed a valid measure of trait self-control (Tangney et al., 2004) to enable preliminary exploration of any effect on action plan formation.

Primary Research questions

Do participants find the trial acceptable and is it feasible?

Does the web-based intervention support the production of good quality action plans?

Secondary research questions

Is there a relationship between trait self-control and quality of action plans?

Are there any changes in self-report contraceptive pill and condom use mishaps at three-month follow-up in each intervention arm?

Method

Design

This was a two-armed parallel group pilot randomised controlled trial with 1:1 allocation ratio (trial registration number: [researchregistry2549](https://www.researchregistry.com/record/2549)). As a pilot trial, primary outcomes were feasibility and acceptability outcomes of completion of measures, attrition to follow-up and completeness and quality of implementation intention plans. Secondary outcomes were self-reported contraceptive pill or condom ‘mishaps’ in the past three months, contraceptive pill or condom use intention, attitude toward contraceptive pill or condom use, perceived behavioural control over pill or condom use, subjective norm relating to pill or condom use and a measure of trait self-control.

Participants and procedure

Demographic information for participants is provided in table 1.

INSERT TABLE 1 HERE.

Ethical approval for this study was granted by Coventry University Research Ethics Committee and Coventry NHS Research Ethics Committee (reference 10/H1210/11) before data collection began. A priori sample size calculations using G Power software suggested that in order to detect a small effect size with power held at .90 and alpha at 0.05 a total sample size of 528 would be required in a full trial. It was decided that we would target recruitment of 100 participants in order to estimate likely time and resources required for a full trial. Participants were recruited from an integrated sexual health service in the UK Midlands by the first author, and all relevant clinical staff were fully briefed about study

requirements. Participants were notified about the study via posters in the waiting area and by leaflet and brief verbal introduction during initial consultation with a member of clinical staff. In order to be eligible for the study, participants had to be aged between 14 and 24 years, currently sexually active, or planning to be soon, and currently accessing or planning to access either one or both of the contraceptive pill and condoms. Potential participants who expressed interest and believed themselves to be eligible were directed to a private room where the first author checked eligibility, explained the study in more detail, answered any questions and completed consent procedures. Participation took around 10-15 minutes and involved being seated in front of a laptop in the private research room with headphones plugged into the computer. After providing contact details for follow-up and passing these to the researcher, participants completed baseline measures and were randomised to either the intervention or control condition by the computer software. Participants were contacted for three-month follow-up measures on-line a total of three times via one or both of email or text (as preferred).

Measures

Participants were asked to identify which of either condoms or the pill they considered to be their main method of contraception and to answer all further questions in relation to that method. Main method use was measured with the question, 'How good have you been at using your main method in the last three months?' Response items were, 'Always used it and never had any problems'; 'Had one mishap in the last three months'; 'Had two mishaps in the last three months'; 'Had three mishaps...'; 'Had four or more mishaps...', scored 0, 1, 2 and so on. A note was included with the question explaining that a 'mishap' included any instance of 'a condom breaking or coming off during sex', 'a condom was not used during part or all of the sex', 'a contraceptive pill was missed and a condom was not used during every occasion of sex for the next seven days' during the specified time frame. This follows one of the formats for behavioural measures (adapted for the context) recommended by Ajzen (2006).

Intention to use main method was assessed with three items on seven-item Likert scales anchored 'strongly agree' to 'strongly disagree' following guidance by Ajzen (2006) but adapted for relevance to both pill and condom use. Items were phrased, 'I want/plan/intend to use my main method effectively over the next three months so that I am protected every time I have sex'. A composite of these items showed good internal reliability ($\alpha = .953$).

Attitude towards main method use was assessed as recommended by Ajzen (2006) using five semantic differential seven-item Likert scales starting with 'For me, using a condom every time I have sex / taking the contraceptive pill every day in the next three months is...(extremely important – extremely unimportant; extremely worthwhile – extremely worthless; extremely good – extremely bad; extremely satisfying- extremely unsatisfying; extremely pleasant – extremely unpleasant). The items showed good internal reliability ($\alpha = .884$).

Perceived behavioural control was assessed by three items on seven-item Likert scales. Items included, 'How much personal control do you have over using a condom every time you have sex / taking the contraceptive pill every day in the next three months?' anchored 'Complete control' to 'no control at all'; 'How confident are you that you can use a condom every time you have sex / take the contraceptive pill every day in the next three months?' anchored 'extremely confident' to 'not at all confident'; and 'I am in complete control over using a condom every time I have sex / taking the contraceptive pill every day in the next three months' anchored 'very strongly agree' to 'very strongly disagree'. Internal reliability of these items was satisfactory ($\alpha = .93$).

Subjective norm was also assessed in line with Ajzen's (2006) recommendations for injunctive measures, with three items on a seven-item Likert scale. Items included, 'Most people I know would approve of me using a condom every time I have sex / taking the contraceptive pill every day in the next three months', anchored 'very strongly agree' to 'very strongly disagree'; 'Most people I know would want me using a condom every time I have sex / taking the contraceptive pill every day in the next three months', anchored 'very strongly agree' to 'very strongly disagree'; and 'People who are important to me would...(anchored 'very strongly approve' – 'very strongly disapprove')...of me using a condom every time I have sex / taking the contraceptive pill every day in the next three months. Items showed good internal consistency ($\alpha = .94$).

Finally, trait self-control was measured using a short, validated scale (Tangney, Baumeister & Boone, 2004).

Intervention

The intervention was comprised of a brief tailored web-based programme created in Adobe Captivate and a paper-based action planning card. Tailoring in the on-line programme was specific to gender selected and main method of contraception (pill or condoms) identified. The content in each case uses characters with audio to take the user through the

process of identifying environmental cues to key target behaviours, and making a plan to perform those behaviours when the environmental cue is present. The range of behaviour change techniques included mapped to theoretical constructs is set out in supplementary file 1. The target behaviours were accessing condoms regularly (to increase chances of having them when needed); mentioning condoms to your partner when sex is imminent; and taking the contraceptive pill at the same time each day. Males were automatically routed through the condom accessing and mentioning pathway. Females could opt to follow the condom or contraceptive pill pathway. The intervention is available to view online at the following address [web address to be inserted here]. Research documenting usability testing of the intervention has been published previously (Brown, Abraham, Joshi & Wallace, 2012). Participants were prompted to write their action plans on the appropriate planning card provided (see figure 1). Control participants simply completed measures and received usual clinic care. Randomisation to either intervention or control was built into the hosting web platform by the web developers. As participants completed their baseline measures online they were directed to the study website which applied an algorithm to direct them to either the intervention or to a page thanking them for participation and directing them to alert the researcher that they had finished. Blinding to intervention condition was not possible.

INSERT FIGURE 1 HERE

Analysis for primary research questions

To assess acceptability of the study we looked at the proportion of participants who were willing to consent relative to the total identified as eligible and given information about the study. We also looked at numbers willing to provide contact details to be followed up electronically and numbers who responded to provide follow-up measures vs. those lost to follow-up. Drop-out analyses assessed whether participants lost to follow-up differed on key socio-demographic measures from those who remained in the study.

Feasibility of the study for a future randomised trial was assessed based on the acceptability measures outlined above and an assessment of the recruitment rate achieved relative to the potential for recruitment based on total number of clinic attendees during data collection periods. This data was used to assess likely time and resources required for recruitment to a full trial. Randomisation checks were also applied to assess whether the randomisation algorithm worked in achieving intervention and control groups with participants that did not differ significantly on key socio-demographic factors.

The manual used to assess plan quality is provided in supplementary file 2.

Participants who scored 9 out of 14 or above were considered to have completed sufficiently good plans that were both goal-directed and completed with sufficient specificity.

Analysis for secondary research questions

Bivariate correlations were used to consider the relationships between the variables measured, in particular the relationship between trait self-control and plan quality. Means and standard deviations of measures were calculated in order to assess numbers of mishaps and any changes reported at follow-up in each intervention arm.

Results

Trial acceptability and feasibility

Participant flow is represented in the CONSORT diagram in figure 2. One hundred and two potential participants identified as eligible by clinic staff were directed to the research room, over a four-month period with data collection sessions of 3-4 hours per week. Of those initially identified, 14 people either declined to participate (n=11) or were not eligible (n=3). Reasons for declining included not being interested (n=4), and being concerned about missing being called for further consultation or test results (n=7). Eighty-eight participants provided full informed consent, completed baseline measures and were randomised to either the control (n=43) or intervention condition (n=45). Sixty-seven participants responded after three contact attempts (one per week over three weeks) at three-month follow-up.

INSERT FIGURE 2 HERE.

Participation in the study appears to have been acceptable to clinic attendees. Of the 102 who reached the research room, 86.3% agreed to take part and provide contact details for follow-up. Many commented that they might as well take part since they needed to stay in clinic and wait for a further consultation with a clinician anyway. Of those who completed baseline measures, provided contact details for follow-up and were randomised to receive either the intervention or usual care, 76.1% provided follow-up measures, representing relatively low attrition.

Analyses assessed whether participants who dropped out of the study and did not provide time 2 follow-up data differed from those who remained in the study on the same key variables as above. An independent t test showed that participants did not differ by age ($t=1.059$; $df=84$; $p=.292$). Chi-square analyses showed that dropping-out vs. providing follow-up data was not significantly associated with sexual orientation (straight vs. not straight) of participants ($\chi^2=1.158$, $df=1$, $p=.282$); nor with ethnicity (white British vs. not white British) of participants ($\chi^2=2.46$, $df=1$, $p=.62$); nor with frequency of sexual activity (at least weekly vs. less than weekly sex) of participants ($\chi^2=.384$, $df=1$, $p=.54$).

It took around 63 research hours in total (one researcher spending 3-4 hours per week over 18 weeks) to recruit 88 participants at baseline. The clinic in question sees around 80 patients on average in a four-hour period, and the 102 who were identified by staff as eligible over the 18 weeks therefore represents about 8% of people who would have been through the clinic during recruitment periods.

In order to assess whether randomisation was effective a series of analyses were conducted to check whether participants assigned to intervention vs. control differed on key variables: age, sexual orientation, ethnicity and frequency of sex. An independent t test showed that participants did not differ by age ($t=.169$; $df=72$; $p=.866$). Chi-square analyses showed that assignment to intervention condition was not significantly associated with sexual orientation (straight vs. not straight) of participants ($\chi^2=.596$, $df=1$, $p=.44$); nor with ethnicity (white British vs. not white British) of participants ($\chi^2=2.9$, $df=1$, $p=.09$); nor with frequency of sexual activity (at least weekly vs. less than weekly sex) of participants ($\chi^2=.576$, $df=1$, $p=.45$).

Quality of action plans

The plan quality manual can be found in supplementary file 2. It takes account of any attempt to complete a plan, instrumentality of the plan, and specificity of either one or both of contextual cues and/or behavioural responses (in the case of mentioning condoms).

Co-authors assessed a sample of 10% each applying these criteria and following discussions to resolve any discrepancy reached consensus over the application of scoring principles. The first author then applied agreed criteria to the remaining sample. The mean score for plan quality was 9 with a standard deviation of 3.13. Plans scoring 9 and above are considered of sufficiently high quality. Examples of good and poor plans for each target behaviour are provided in table 2 below. A total of 18 were classified as 'poor' and 27 as 'good'. The main

reason for failing to score points was lack of specificity of contextual cues and failing to identify a daily or weekly routine (for accessing condoms and pill use). Given the reasonably high proportion of action plans identified as ‘good’, it is reasonable to conclude that the simple computer application and planning cards provided do support most users (61%) to produce a good quality action plan related to use of or preparatory behaviours related to their self-identified main method; contraceptive pill or condoms.

INSERT TABLE 2 HERE.

Analyses relating to secondary research questions

Table 3 provides the bivariate correlations between all variables included in the analysis. The theoretical relationships between these variables are also illustrated in figure 3. As would be expected, there are statistically significant positive correlations between all TPB (intention, attitude, PBC and subjective norm) variables. The only TPB variable however that is statistically significantly related to the self-reported behavioural outcome (mishaps) is PBC. The statistically significant negative correlation demonstrates that as mishaps decrease (indicating effective contraceptive method use is more consistent) PBC increases.

The bivariate correlations show a statistically significant negative relationship between trait self-control and plan quality. This suggests that as trait self-control increases, plan quality decreases. Plan quality is not related however to number of mishaps reported at baseline.

INSERT TABLE 3 AND FIGURE 3 HERE

Bivariate correlations in table 3 show that self-reported mishaps are statistically significantly negatively correlated with trait self-control. As number of mishaps decrease, trait self-control increases.

Consultation of the mean scores by time and condition in table 4 suggests that the number of self-reported mishaps with participants’ main method of contraception is reduced by time two in the intervention condition compared to controls. Mean scores for other variables from the TPB do not appear to differ by time or condition.

INSERT TABLE 4 HERE

Discussion

The primary aims of this pilot randomised controlled trial (RCT) were to assess the acceptability and feasibility of a potential future definitive RCT assessing efficacy of a digital action planning intervention to reduce condom and contraceptive pill use mishaps. The study involved patients in an integrated sexual health clinic in the UK Midlands. We were interested in whether participants were willing to be recruited to the study; provide contact details for follow-up; complete follow up measures sent electronically at three-month follow-up; and whether those who were lost to follow-up differed significantly on key demographics from those retained. In addition, the study aimed to assess whether the intervention supported production of good quality action plans; whether a validated measure of trait self-control was associated with quality of plan produced; and whether there were any changes in self-reported mishaps at follow-up amongst intervention participants compared to controls.

Given that 86.3% of people identified by clinic staff agreed to participate, be randomised and provide follow-up contact details, it appears that study participation was reasonably acceptable to clinic attendees. Attrition was also low with 76.1% providing follow-up measures. Based on average numbers of clinic attendees seen during the recruitment sessions it is estimated that for every hour that was spent in recruitment and study delivery approximately one participant was recruited and retained to follow-up. The initial recruitment rate is comparable to a similar feasibility study conducted within three sexual health clinics. Bailey, Webster, Griffin et al. (2016) took approximately ten weeks over three sites to recruit 159 participants for the Men's safer sex feasibility trial. Martin et al., (2009, 2011) who also recruited in a clinic setting achieved baseline participation of 261 adolescent women over 11 weeks but did so with the support of 19 clinic staff involved in recruitment. A future full trial of the current intervention conducted in a UK setting could apply to be accepted onto the National Institute for Health Research (NIHR) portfolio and receive support for recruitment. NHS trusts in the UK are incentivised by financial reward for adopting research studies to their local portfolio and supporting recruitment to time and target (NIHR CRN portfolio, no date; Brown & Fulton, 2012). The current pilot study was not on the local portfolio and recruitment success may be attributable to the strong support from within the clinic setting. What is not known is whether clinic staff identified all the eligible patients during recruitment sessions and asked them about willingness to visit the research room to find out more, and if they did, what proportion declined to do this. Resources did not

allow for collation of this information during this study, but where possible to do so should be included in future study designs.

The relatively low attrition compares favourably to the feasibility study by Bailey et al. (2016) which achieved just 37% (of 159 participants) at 3-month follow-up in their digital clinic-based feasibility study of the Men's safer sex trial, and this included a £10 voucher payment for measure completion. Their study however, included a greater number of measures and a more time-consuming intervention engagement requirement (a whole website for self-directed exploration). The authors reported that a third of intervention participants did not engage with the intervention (Bailey et al., 2016), and that technical problems in the early stages of the study may have discouraged some from further participation (Bailey et al., 2016). In the current study, intervention access did not rely on clinic Wi-Fi (we were plugged into the network) and baseline measures and intervention engagement were completed under researcher supervision at the same time as recruitment. Another digital feasibility trial in the field of smoking cessation produced similar follow-up rates to the current study with 75% of the 87 participants randomised completing follow-up measures (Powell, Newhouse, Martin et al. 2016). They reported slow initial recruitment rates however, meaning data collection for a full trial would take time and could be costly. Certainly, our own *a priori* power calculations and the data presented here suggest that around 550 hours of researcher time would be required to recruit and retain the number of participants needed to adequately assess efficacy in a future definitive trial.

Plan quality was assessed using clear criteria that enabled authors to reach agreement over scores, and a majority of plans (61%) were identified as meeting the criteria for being rated as 'good' with a score of nine out of 14 or above. This suggests that the intervention was moderately good at supporting people to produce high quality plans, but that improvements could be made. For example, there was some variation in the structure of the content on planning cards and what participants were prompted to write across the three behaviours. This was partly because of the varying nature of the behaviours (e.g. condom mentioning needs to happen in the sexual context and locations cannot be predicted, whereas location of access can be). Greater consistency of guided plan structure and greater consistency of examples (cf Reinwand et al., 2016) may support even more participants to produce highly specific plans linked to existing relevant routines.

The findings on plan quality reflect those of de Vet et al. (2011) to some extent, in that they found young women were able to produce good quality plans for preparatory condom behaviours (e.g. buying, carrying, and discussing condoms) but not condom use.

They therefore recommended that implementation intentions for condom use should include plans for preparatory behaviour. In the present study, participants, both male and female were similarly mostly able to produce quality plans for either contraceptive pill use or accessing condoms and mentioning condom use at an appropriate moment. An as yet unexplored area of investigation with regards action planning in the context of safer sex behaviour is the effect of dyadic planning. Research looking at the effects of action planning on physical activity behaviour has identified that making a plan with a partner is linked to higher levels of plan enactment (Keller et al., 2017; Knoll et al., 2017). Consideration of social aspects of planning including dyadic planning has also been recommended as a priority for future research in the field of action planning and implementation intentions (Hagger, Luszczynska, de Wit, et al., 2016). Given the dyadic nature of sexual behaviours there is likely to be good potential of dyadic planning by couples in a sexual relationship with one another.

The relationships identified by the bivariate correlations were of interest (see table 3). In particular, perceived behavioural control has a small but significant relationship with both trait self-control and number of mishaps reported, whilst intention is not related to these variables. This relationship suggests that it may be important to address perceived behavioural control as well as support action planning within intervention content in this population. Trait self-control is related to both plan quality and number of self-reported mishaps, and in relation to plan quality this is in an unexpected direction. The greater the capacity for self-control of the participant, the lower the quality of their action plan. A possible explanation for this is that those with greater capacity for self-control put less effort into their action plan within the study because they felt it was unnecessary. Certainly the significant negative relationship between number of mishaps and self-control suggests those with greater abilities in this area are more effective users of their chosen method anyway. Encouragingly, consideration of the mean scores of participants by time and intervention condition showed some indication the intervention may be helping clinic attendees to reduce experiences of contraceptive pill and condom use mishaps. All of these early indicators require further exploration in future research.

Strengths and Limitations

In addition to some of the limitations already highlighted above, there are a number of further limitations that must be taken into account in assessing the findings. First, the study relied on self-report measures of contraceptive and condom mishaps, and these have been well-documented as problematic in relation to pill use (Potter, Oakley, de Leon-Wong, &

Cañamar, 1996). Clearly, objective data in addition to self-reported behavioural outcomes are preferable and have been successfully incorporated in other clinic based studies in this field (e.g. Bailey et al., 2016; Martin et al., 2009; 2011). Resources for the present pilot study were limited however, and the additional cost in time and resources of clinic staff to achieve this was not available. A future larger scale trial of this nature should include objective assessments of clinical outcomes such as STI screening and positive STI diagnoses, and with NIHR portfolio support this ought to be possible. Related to this, is the fact that number of mishaps recorded were not controlled against number of opportunities for a mishap, which we have identified as problematic. In subsequent work (Kehal, Newby, Johnson & Brown, in preparation) we have developed a measure of relative risk based on a number of factors including frequency of sexual activity and number of times mishaps occur relative to this which we would apply within a future RCT.

A further limitation was that there was only one three-month follow up and no data was collected longer term than this. It has been recommended that future research investigating implementation intentions should include longer term follow up as these data are largely lacking from the literature (Hagger & Luszczynska, 2014). Recent research has also suggested that two-month post-intervention may be optimal for initial electronic follow-up measures to be sent to participants following exposure to an on-line intervention (Fulton, Brown, Kwah, et al., 2017).

In relation to the study measures, for those included from the TPB, some adaptation of the principles for measure construction (Ajzen, 2006) was applied in order to make measures relevant to the three different behaviours included in the study. This may have affected the quality and precision of the data collected and in a future definitive trial this should be addressed by providing separate measures for participants responding in relation to different contraceptive methods and target behaviours. In addition, the phraseology of the measures relating to mishaps could be considered leading, as they begin with, 'How good have you been at...'. A future trial should aim to use more neutrally phrased items focussed purely on the behaviour (e.g., 'How frequently have you...').

Further limitations include the fact that blinding was not possible and this could be addressed in future trial designs in order to reduce bias. Producing a comparable control condition rather than just usual care would reduce the likelihood of participants knowing how they had been randomised, and it may be possible under such circumstances to also blind the researcher to condition allocation if participation timings were equivalent and they could not see the participants' screen. In addition, although the randomisation algorithm applied in the

current study appears to have been effective, the technician responsible for this did not provide information about how this was achieved and has since left the institution leading the study. This was an oversight and should be addressed in any future studies.

Finally, we relied on quantitative assessments of study acceptability and did not engage study participants or staff in qualitative process evaluation methods. This was less than ideal, and was again largely due to resource issues. Had we conducted follow-up interviews with study participants and staff we could have learned much more about the reasons for engagement and drop-out, and the factors that supported people to produce quality action plans.

Strengths of the present study include that it is amongst relatively few examples of attempts to assess behaviour change interventions in real-world contexts, and the first action planning intervention to focus on three sexual health related behaviours and two contraceptive methods using digital delivery in a clinic context. The challenging nature of research in this context meant a pilot trial (with trial registration) was warranted and as a consequence, a number of considerations for the implementation of a future trial have been identified and outlined above. The inclusion and pilot assessment of a potential moderator (trait self-control) of action planning effects, so as to better understand for whom action planning may work best also addresses a priority for research in this area (Hagger & Luszczynska, 2014; Hagger, Luszczynska, de Wit et al., 2016) and has identified a relationship that may be of interest for further investigation in a future trial.

Conclusions

This pilot randomised controlled trial has demonstrated reasonable levels of acceptability and feasibility for evaluating this digital planning intervention to support contraceptive pill use, and condom use preparation behaviours in 14 to 24-year-old integrated sexual health clinic attendees. The intervention appears to support both pill and condom users to produce quality action plans; though some scope for improving content to further improve plan quality has been identified. Bivariate correlations suggest there may be a role for addressing perceived behavioural control over method use within intervention content and that having greater levels of trait self-control may negatively affect plan quality. Further exploration of this is required in future work. There are early indications that the intervention may help participants to reduce the numbers of mishaps they have with the most popular methods of contraception used by young people. There could be significant clinical potential

for systematically embedding action planning in sexual healthcare using digital solutions and further definitive trials are needed.

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Accepted Manuscript.

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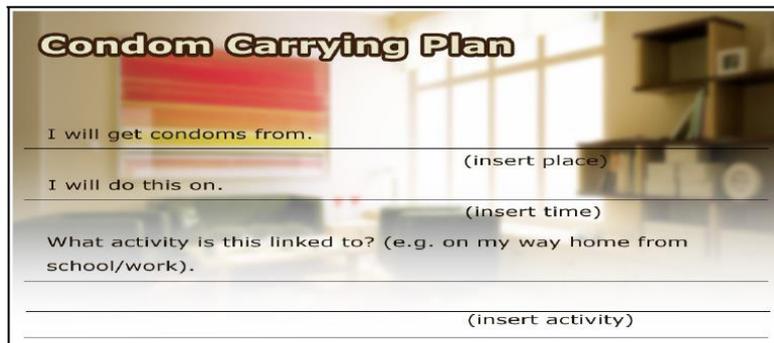
Table 1

Descriptive information for participants at baseline and follow-up

Variable	Baseline (N=88)	Follow-up (N=67)
Age range	14-24 years	15-24 years
Mean age (and standard deviation)	20.27 years (2.48 years)	19.63 years (1.92 years)
Sexual orientation		
Straight	73	58
Gay	5	3
Bisexual	7	6
Other	3	0
Ethnicity		
White	59	46
Black	14	11
Asian	8	6
Chinese	2	1
Mixed	2	2
Other	2	1
Missing	1	0
Relationship status		
Single (no partners)	20	17
Single (has sexual partners)	27	22
In a relationship	28	19
Living with someone	7	4
Missing	6	5
Frequency of sexual activity		
No sex in last 6 months	4	2
Sex a few times in last 6 months	19	22
At least monthly sex	24	16
At least weekly sex	38	29
Missing	3	0
Main contraceptive method		
Pill	32	25
Condom	39	31
Other (e.g. implant) but also uses condoms	11	9
Missing	4	2

Figure 1

The action planning cards provided to participants in the intervention condition, prompting them to make appropriate cue related plans.



Condom Carrying Plan

I will get condoms from. _____ (insert place)

I will do this on. _____ (insert time)

What activity is this linked to? (e.g. on my way home from school/work). _____

_____ (insert activity)



Condom mentioning Plan (female)

Think about the behaviour you have just chosen.
Think about the phrase you want to use.

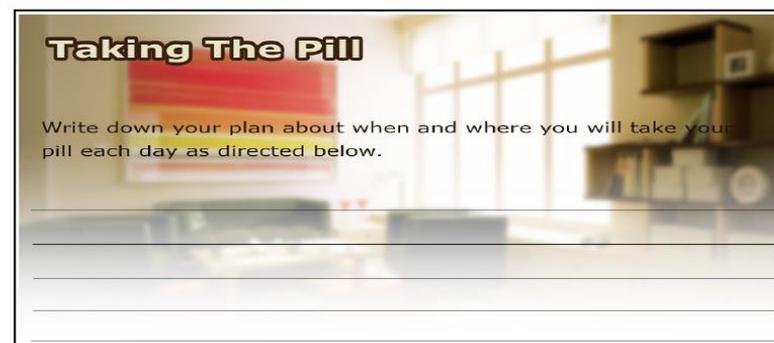
Write down your decision about mentioning condoms as directed.



Condom mentioning Plan (male)

Think about the behaviour you have just chosen.

Write down your decision about mentioning condoms.



Taking The Pill

Write down your plan about when and where you will take your pill each day as directed below.

Table 2

Examples of good and poor implementation intention plans for three target behaviours

Target behaviour	Good examples	Poor examples
Condom Carrying	“I will get condoms from the family planning clinic. I will do this on Fridays at 4pm after work on my way home.”	“I will get condoms from the health centre pharmacy on my way home from college” (Does not specify when)
Condom mentioning	“Whenever I am kissing in bed I will raise issue of condoms saying: ‘do you have any condoms?’ Or ‘Let me put a condom on you’. If we don’t use a condom then I don’t want to have sex.”	“Do you have condoms with you? – Saying.....Kissing in bed – behaviour” (Lacks the commitment-like phrasing)
Taking the Pill	“I will take my pill at 7.30am in the bathroom after brushing my teeth”	“In my makeup bag” (Does not specify when and where and with what other activity)

Table 3.

Bivariate correlations for all measures at baseline (T1)

Measure (Range)	PQ (N=44)	Int (N=85)	Att (N=82)	PBC (N=82)	SN (N=85)	MisH (N=86)	Trait SC (N=86)
Plan quality (PQ)	1	.048	.085	-.207	-.175	-.016	-.444*
Intention (1-7)		1	.794**	.443**	.663**	-.001	.079
Attitude (1-7)			1	.614**	.689**	-.186	.361*
PBC (1-7)				1	.664**	-.357*	.313*
Subjective Norm (1-7)					1	-.007	.089
Mishaps (0-4)						1	-.437**
Trait self-control (1-5)							1

**Significant at $p < .001$ *Significant at $p < .01$

Table 4.

Means and (standard error) for participants scores at T1 and T2 by condition

Measure (Range)	Baseline (T1)		Follow-up (T2)	
	Control (N=43)	Intervention (N=45)	Control (N=33)	Intervention (N=34)
Intention (1-7)	6.13 (.223)	6.53 (.220)	6.76 (.050)	6.70 (.049)
Attitude (1-7)	5.07 (.175)	5.43 (.172)	4.93 (.073)	4.93 (.072)
PBC (1-7)	4.99 (.167)	5.55 (.167)	5.47 (.084)	5.41 (.083)
Subjective Norm (1-7)	5.31 (.173)	5.71 (.170)	5.56 (.065)	5.51 (.064)
Mishaps (0-4)	1.14 (.623)	.985 (.218)	1.29 (.583)	.625 (.490)
Trait self- control (1-5)	3.48 (.523)	3.63 (.499)	3.25 (.226)	3.30 (.189)

Accepted Manuscript.

Article accepted for publication in *Applied Psychology: Health and Well-Being*, 09/09/2018.