Provision of the progestogen-only pill by community pharmacies as bridging contraception for women receiving emergency contraception: the Bridge-it RCT

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Scientific summary

The Bridge-it RCT

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Scientific summary

Background

Most women who use emergency contraception in the UK access it from a community pharmacy. It is important that women start an effective ongoing method of contraception after emergency contraception if they do not want to become pregnant. However, pharmacists cannot usually provide contraception (except condoms) without a prescription. This means that to start an effective contraceptive (e.g. implant, oral contraceptive pill, etc.) women must go to a general practitioner or a sexual and reproductive health clinic. Getting an appointment is not always easy and can take time, and some women become unintentionally pregnant during this time. This trial aimed to test whether or not a community pharmacy-based intervention designed to facilitate uptake of effective contraception after emergency contraception increased the uptake of effective contraception 4 months later, compared with standard care alone. The intervention consisted of a supply of the progestogen-only pill plus the invitation of rapid access to a sexual and reproductive health clinic. The hypothesis was that the progestogen-only pill would provide temporary contraception (known as 'bridging contraception') until women could obtain their preferred method of contraception from a general practitioner or a sexual and reproductive health clinic. The rapid-access component facilitated access to a local sexual and reproductive health clinic where a full range of methods of contraception were available.

Design

This was a pragmatic cluster randomised cohort crossover trial. Community pharmacies were cluster randomised to provide the intervention followed by control or vice versa. The Bridge-it study included a multimethod process evaluation to assess implementation, mechanisms of change and context to better understand the effectiveness of the trial.

Setting

Twenty-nine community pharmacies in Scotland and England (Lothian, London and Tayside).

Target population

The community pharmacist assessed the medical eligibility of women (aged $\geq$ 16 years) presenting for emergency contraception and provided this (levonorgestrel) in accordance with normal practice.

Health technologies being assessed

The intervention consisted of provision of a 3-month supply of the progestogen-only pill (75 µg of desogestrel provided by pharmacists using a patient group direction) to be started the day after emergency contraception, together with a rapid-access card, which, on presentation at the local sexual and reproductive health clinic, helped women to be seen as a drop-in patient for advice and the provision of ongoing contraception, including long-acting reversible methods (i.e. implant, intrauterine and injectable). The control was standard care (which was advice about accessing ongoing contraception from a general practitioner or sexual and reproductive health clinic) with emergency contraception from the pharmacy. Standard care was characterised by a mystery shopper exercise that was undertaken in participating pharmacies before the control period of the trial.

Methods

In the intervention group, pharmacists provided women with the progestogen-only pill and instructions for its use. In addition, pharmacists advised women that on presenting the rapid-access card to the local sexual and reproductive health service they would be seen as a drop-in patient for ongoing contraception. In the control group, pharmacists advised women to go to their general practitioner or a sexual and reproductive health clinic for ongoing contraception. All women completed a questionnaire on their method of contraception at 4 months. This was completed as a telephone interview with a research nurse or, if preferred, by a self-completed web-based survey. Serious adverse events were also collected at this 4-month follow-up. The main analysis was based on the intention-to-treat principle. Baseline and follow-up data were summarised using the mean (standard deviation) or median (interquartile range), where appropriate, for continuous variables. Discrete variables were summarised with numbers and percentages. The primary outcome (i.e. the proportion of events in each cluster period) was analysed using linear regression, with cluster as a fixed effect. The main analysis was adjusted for mean age, percentage of participants who are in an ongoing sexual relationship and percentage of participants who have used effective contraception methods previously.

A process evaluation of the intervention was conducted to assess implementation, fidelity and reach. The process evaluation comprised quantitative and qualitative data collection, including review of training materials; observation of training; protocol adherence checklists, and recruitment and monitoring forms; and semistructured telephone interviews with participants ($n = 36$), pharmacists ($n = 22$) and sexual and reproductive health service providers ($n = 5$). A standardised training observation form was used to guide observations, with data transcribed into Microsoft Word (Microsoft Corporation, Redmond, WA, USA), thematic analysis conducted and descriptive summaries written. Thirteen training sessions in Scotland were observed by the process evaluation research assistant and the study trainers completed the observation forms after each training session in London. Relevant data from the pharmacist eligibility screening logs and from the 4-month follow-up surveys were entered into statistical software package IBM SPSS Statistics V.25 (IBM Corporation, Armonk, NY, USA) and descriptive analysis was conducted. Interview data were audio-recorded, transcribed verbatim and anonymised. Data analysis was undertaken using 'framework analysis', a method with proven validity and reliability, to ensure systematic thematic analysis and to facilitate synthesis of key themes. Constant comparison was carried out to ensure that the analysis represented all perspectives and negative ('deviant') cases. All process data were analysed independently from the outcome data and were documented before the outcomes were known.

Outcomes

The primary outcome was self-reported effective contraception use (hormonal and intrauterine) at 4 months (intervention group vs. control group). Subanalysis was use of long-acting reversible contraception in both groups. Secondary outcomes included cost-effectiveness of the intervention (to be reported later) and the proportion of women in each group having undergone an abortion within 12 months, using record linkage from participants to national registries (to be reported later). Process evaluation examined the reasons that the intervention worked or did not work to inform any future implementation.

Results

The study took place December 2017 and June 2019 and recruited 636 women to the intervention ($n = 316$) and control groups ($n = 320$). There were no statistically significant differences in demographic characteristics between the groups. Four-month follow-up data were available for 198 (63%) women in the intervention group and 208 (65%) women in the control group. The proportion of participants reporting use of effective contraception was 20.1% greater (95% confidence interval 5.2% to 35.0%)

in the intervention group (58.4%, 95% confidence interval 48.6% to 68.2%) than in the control group (40.5%, 95% confidence interval 29.7% to 51.3%) (adjusted for recruitment period, treatment arm and centre; $p = 0.011$). The proportion of women using effective contraception remained statistically significantly larger when adjusted for age, current sexual relationship and history of past use of effective contraception, and was robust to the missing data. Long-acting reversible contraception method use was not statistically significantly different between the intervention group (13/198, 6.6%) and the control group (23/208, 11.1%) (95% confidence interval −10.04% to 1.05%; $p = 0.112$).

The mystery shopper exercise undertaken to describe 'standard care' for the control group, concerning the request for emergency contraception at a community pharmacy, showed that, although pharmacists were generally helpful, obtaining emergency contraception was not always easy, waiting times were sometimes long, consultations were short and privacy was not always guaranteed. In addition, less than half of the pharmacists in the mystery shopper exercise gave any advice about ongoing contraception.

In the process evaluation, the accessibility and convenience of the pharmacy setting was highlighted as pivotal to making effective contraception more accessible. The intervention was acceptable to pharmacists and sexual and reproductive health providers, and was seen as an important way to develop and improve access to contraception and reduce repeat emergency contraception use. Reflections of implementation indicate that fidelity of delivery was, on the whole, achieved in the pharmacy context. A range of cross-cutting challenges to implementation emerged that were specific to the community pharmacy and the sexual and reproductive health context (e.g. high workloads, understaffing, changing priorities), which had an impact on delivery. Participants' accounts highlighted that providing a bridging supply of the progestogen-only pill with emergency contraception from the pharmacy as routine practice may have a positive impact on knowledge of contraception and contraceptive practices in the short term and, potentially, in the longer term by overcoming existing barriers to access and increasing confidence in accessing contraception and managing risk. Persistent barriers to accessing and using routine effective contraception remained, including worries about side effects, concerns about the commitment required, ingrained stigma related to accessing sexual health clinics, and difficulties accessing repeat prescriptions and appointments for continued contraceptive care. Such barriers are important to consider in wider implementation of bridging as a service.

Conclusion

Provision of a bridging supply of the progestogen-only pill with emergency contraception from a community pharmacist and the invitation to a sexual and reproductive health clinic result in a significant increase in subsequent reported use of effective contraception. This simple intervention has the potential to help prevent unintended pregnancies for women after emergency contraception. As well as being acceptable to pharmacists, sexual and reproductive health providers and participants, bridging as a practice seemed feasible in the pharmacy setting, despite existing contextual challenges. This suggests that the practice could be widely implemented and routinely embedded in community pharmacies, with some adaptations to alleviate challenges and recurrent barriers to long-term use of effective contraception to encourage greater uptake. Suggestions to increase uptake of bridging contraception in the pharmacy setting include greater advertising and promotion of the service, provision of non-judgemental and supportive contraceptive consultations, an option to book routine contraceptive consultations in pharmacies outside of emergency contraception consultations and increasing the bridging contraceptive options available.

The findings of the mystery shopper study suggest that opportunities to provide emergency contraception to women and to prevent unintended pregnancy are currently being missed in community pharmacies across the UK. Lack of resources and changing priorities in the pharmacy and sexual and reproductive health contexts highlight the need for sufficient resources and time to administer any enhanced emergency contraception service and for it to be embedded in routine practice. Use of the rapid-access invitation to

sexual and reproductive health services was limited and sexual and reproductive health services faced challenges during the time of study, with funding cuts to services (London) that may have restricted access to contraception for women. It is also possible that many women preferred to access contraception from their general practitioner and that the perceived stigma of attending a sexual and reproductive health service is still a barrier. The rapid-access invitation may be a less important component of the intervention than the supply of the progestogen-only pill and therefore community pharmacies signposting to contraceptive services may suffice.

The intervention tested in this study (i.e. a 3-month supply of the progestogen-only pill) should not be a costly one, as the progestogen-only pill is an inexpensive drug, but this will be determined by a cost-effectiveness analysis, which is under way but not yet completed.

The main limitation of this study is that the outcome was uptake of effective contraception rather than unintended pregnancies. We had originally intended to examine abortion rates in each group as a co-primary outcome, but during the study it became evident that we could not recruit sufficient numbers of participants within a realistic time frame, and so we chose to focus on the uptake of effective contraception. Use of effective contraception should prevent unintended pregnancy. Although participants gave consent to allow subsequent data linkage with abortion registries, the sample size may be too small to show any difference between the groups. Another consideration is that contraceptive use was self-reported; however, there is evidence that women's self-reporting of contraceptive method is reliable. In addition, we had expected loss to follow-up in this study to be 25%, but it was larger at 35%, although there was no difference in rates between the groups. Evaluation of the impact of the intervention would be important following any future wide-scale implementation.

Trial registration

This trial is registered as ISRCTN70616901.

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This report

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