The evaluation of a free-to-access online contraception service in Lambeth and Southwark

Rezel, Emma Claire

Awarding institution:
King's College London

THE EVALUATION OF A FREE-TO-ACCESS ONLINE CONTRACEPTION SERVICE IN LAMBETH AND SOUTHWARK

Emma Rezel

Student ID: 1475210

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Abstract

Unplanned pregnancy is associated with adverse health, economic, social and psychological outcomes for women and children. It can be addressed through improved contraceptive provision. This thesis aims to evaluate a free-to-access online contraception service which involves remote consultation, online information, text support and home-delivered oral contraceptive pills (OCPs), introduced in the London boroughs of Lambeth and Southwark.

A theoretical framework used Bourdieusian sociological concepts to consider contraceptive practice as the product of habitus, which is an acquired system of dispositions reflecting past experiences, traditions and habits that engenders homogeneity in outcomes within social groups and is relationally bound with capital and field. This framed the online service as a new field of access which could attract users of a different habitus to users of existing, face-to-face services, altering capital exchange between patient and provider, such as the knowledge of how to effectively use a method. The overarching theory was integrated with a context-specific, theory of change conceptual model, generated through qualitative investigation of stakeholder views on the service, helping to surface key research questions. A quantitative study described the characteristics and patterns of use of online users in its first period of availability (n=726) and a cohort study collected objective and self-reported data to examine associations between OCP provider type and short-term continuation (n=227).

Almost three quarters of online service-users were aged 20 to 29 years, most were of white ethnic group and the majority from socioeconomically deprived areas. Black, Asian and mixed ethnic groups had lower odds of repeat online orders compared to white ethnic group in bivariate and multivariable analyses. In the cohort study, short-term OCP continuation was more likely for the online group than the other services group and statistical significance was retained after adjusting for background variables. The online group rated their service more highly in terms of convenience, speed of access to OCPs and ease of communication with provider and had similar levels of basic OCP knowledge compared to those using other services.

These are the first findings on free-to-access, online contraception. It may expand choice in access to OCPs to those of the habitus to benefit from its relative convenience and, despite the absence of face-to-face care, may not diminish the conveyance of capital in the form of basic OCP knowledge. Ongoing investment in both online and face-to-face provision is recommended to maximise contraceptive choice. Quantitative studies are needed to examine the effectiveness of online contraception long-term and qualitative work should explore ethnicity as habitus and its role in shaping contraceptive practice. This, and similar technological innovations are likely to proliferate in the current policy context, so it is vital for research to keep pace with change.

Table of Contents

Table of Figures

Table of Tables

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Abbreviations

Abbreviation	Meaning	First Use
BAME	Black, Asian and minority ethnic	2.9.1
BP	Blood pressure	2.10
CCGs	Clinical Commissioning Groups	2.7.1
CIC	Community Interest Company	1.2
CiP-CO	Contraception in Person – Contraception Online	1.4
COC	Combined oral contraception	2.5.1
Cu-IUD	Copper intrauterine device	2.5.2
EC	Emergency contraception	2.5.7
FSRH	Faculty of Sexual & Reproductive Healthcare	4.5.2
IMD	Index of Multiple Deprivation	2.9.2
IUC	Intrauterine contraception	2.6.1
IUS	Intrauterine system	2.5.2
LA	Local Authority	1.2
LARC	Long-acting reversible contraception	1.2
LMUP	London Measure of Unplanned Pregnancy	2.3
LSOA	Lower-Layer Super Output Area	2.9.1
NATSAL	National Survey of Sexual Attitudes and Lifestyles	2.4.1
OCP	Oral contraceptive pill	1.2
POP	Progesterone-only pill	2.5.1
SRHAD	Sexual and Reproductive Health Activity Dataset	6.5.3
SRH	Sexual and Reproductive Health	1.2
STI	Sexually transmitted infection	2.7
TDE	Theory-Driven Evaluation	1.4
ToC	Theory of Change	1.4
UKMEC	UK Medical Eligibility Criteria for Contraceptive Use	2.10
UPSI	Unprotected sexual intercourse	2.5.7

1 Thesis Overview

1.1 Chapter Overview

This chapter is an introduction to this thesis and an overview of the background to the evaluation of free to access, online contraception within the population of Lambeth and Southwark. In addition, this chapter presents the aims and objectives of this thesis and an outline of the included chapters.

1.2 Background

One in six pregnancies in Britain are unplanned (1). Unplanned pregnancy is associated with adverse health, economic, social and psychological outcomes for women and children (2). It disproportionately affects young women (3) and those with higher levels of socioeconomic deprivation (1, 4, 5). Unplanned pregnancy can be reduced through better access to comprehensive contraceptive information and supplies (6, 7). Use of contraception is negatively associated with belonging to an ethnic minority group (8) and living in a more deprived area (5).

National guidelines for the provision of contraception define quality in terms of choice, stating that contraceptive-users should have access to a range of providers, including general practice and alternative, open access, specialist providers, as well as access to the various contraceptive methods (6). This access is available to all, free of charge, from the National Health Service (NHS). Despite this, barriers to access remain, including delays in obtaining appointments (9), concerns over confidentiality (10) and long waiting times (11). It has been posited that these issues have been exacerbated due to severe disinvestment in contraceptive services in community clinics which, since the Health and Social Care Act of 2012 (12), have been commissioned, along with broader sexual health services, by Local Authorities (LAs) rather than NHS England (13, 14). Difficulties in obtaining appointments are a barrier to contraceptive access from general practice (9), which may intensify in the face of unstable service-delivery and growing financial pressures on NHS England (15).

This disinvestment is a marked contrast to the previous decade in which the UK government launched the Teenage Pregnancy Strategy in 1999 (16) and the National Strategy of Sexual Health and HIV in 2001 (17). These were sustained and multifaceted policy interventions including national media campaigns and funding of £26.8 million to increase access to long-acting reversible contraceptives (LARCs). These have been credited with accelerating the decline in the under 18 conception rate in England and Wales to 18.9 per 1000 in 2016; a 10% decline from the previous year and a 60% decline since 1998 (18-20). Whilst these strategies are no longer operational, the learning and some of the action points are now

deeply embedded within Sexual and Reproductive Health (SRH) policy and provision. The importance of access to a range of methods of contraception was highlighted in the Department of Health's "A Framework for Sexual Health Improvement in England", published in 2013 (21). The report also states that opportunities for improvement are available in the form of technology to support self-care and health education. There is a perception that social enterprises are well-placed to seize such opportunities with their apparent prioritisation of innovation, cost-efficiency and responsiveness (22). The current government, as well as those preceding it, have promoted social enterprises in several ways including the £100 million social enterprise investment fund and the publication of reports recommending their advantages to NHS purchasers (23-25).

The online contraception service under investigation in this thesis is called SH:24, and is a type of social enterprise, called a community interest company (CIC), that has been commissioned to provide sexual and reproductive health services in Lambeth and Southwark (and other areas not covered within this thesis). SH:24, like other social enterprises, can be considered as a type of 'hybrid' organisation (26), with primarily social objectives but, theoretically, with the capacity for efficiency and innovation typically seen in the private sector (27, 28). At the time of writing, SH:24's contraception service can be summarised as online information on all contraceptive methods; an online clinical assessment and ordering process to access 3 or 6 months' supplies of either combined or progestogen only oral contraceptive pills (OCPs) for delivery to the service-user's home, at no financial cost, and all supported via text or phone calls between the service-user and provider. There is no precedence in the literature for a contraceptive service which comprises all of these elements and no available evidence for the effects of free-to-access, home delivered OCPs.

Nonetheless, there is much to draw from within the contraceptive literature to develop understanding of the various elements of the online service. Improving contraceptive counselling has long been a focus in the literature including interventions that have sought to improve uptake, adherence and acceptability of contraceptive methods with varying success (29, 30). Increasingly, interventions are being designed to take advantage of the ubiquity of internet-enabled devices and near universal mobile phone ownership (31) to deliver contraceptive counselling digitally or remotely (32-44).

The literature highlights the potential for remote messaging interventions to improve contraceptive knowledge for effective use of contraception. One randomised controlled trial (RCT) assessed the effect of daily text messages on OCP continuation among new OCP users from an urban family planning health centre in the United States (44). At 6 months, effective OCP use was higher in the intervention than the control arm (64% (223/346) versus 54% (182/337), respectively; p=0.005*).* This study was included in Smith et al.'s (2015) review of mobile phone-based interventions which stated broadly promising effects on

contraceptive use and adherence from five RCTs (32). Research on digital decision aids including mobile applications (apps) and online tools indicate a generally high level of satisfaction among pilot testers (36, 37, 39) but more robust studies using RCT designs suggest that these types of interventions may have limited impact on contraceptive continuation (45), uptake and knowledge (42).

These are useful findings when considering remote and digital counselling and education, however, none of the interventions in the literature mirrors the complexity and innovation of the SH:24 service considered in this thesis. Furthermore, there is a lack of evidence with direct relevance to the research context of Lambeth and Southwark. These are adjacent, inner London boroughs with high levels of deprivation and relatively large proportions of ethnic minority groups (46, 47) and some of the highest rates of teenage pregnancy and abortion in the country (18, 48). In line with the national picture, the LAs in these boroughs have cut funding to their face-to-face contraceptive providers and have commissioned SH:24's online contraception service to meet excess demand and broaden choice in access (49). This thesis presents the first findings on the impact of online contraception which will have direct implications for contraceptive service delivery in an area where the public health need for quality, accessible contraception is among the most pressing in the country.

1.3 Thesis Aims and Objectives

This thesis aims to evaluate a free-to-access online contraception service introduced in Lambeth and Southwark and seeks to fulfil the following objectives:

- To set the scene for the research by contextualising the online service within developments in local and national strategies to reduce rates of unplanned pregnancy and the commissioning of contraceptive services.
- To apply elements of Bourdieu's Theory of Practice for the theoretical framework and epistemological approach of this thesis; providing a sociological lens through which to contextualise the relevant background literature and empirical findings.
- To use stakeholder predictions to produce a conceptual framework that depicts the key inputs of the online contraceptive service and the processes of change these could generate within the target population; revealing the assumptions upon which these are based.
- To describe the characteristics of the those who use the online service in its first period of availability and analyse the factors associated with repeat ordering of OCPs.
- To explore whether continuation to a second supply of OCPs is associated with the type of contraceptive service used to obtain an initial 3 months' supply of OCPs.
- To explore whether OCP knowledge and ratings of the quality of service provision are associated with type of contraceptive service used to obtain an initial 3 months' supply of OCPs.

1.4 Overview of Chapters

Chapter 2 provides the rationale for the research in terms of the issue of unplanned pregnancy and its adverse effects. It uses evidence from the latest observational research to establish rates of unplanned pregnancy nationally and locally and considers the factors associated with this, and related outcomes. It sets the scene for the research by outlining contraceptive provision in the UK with regard to available methods, services and some of the pivotal, national strategies that have had widespread impact on contraceptive uptake and use. It also contains a literature review which considers the evidence base for digital and remote solutions to address the barriers to effective contraceptive use. Finally, this chapter introduces SH:24's online contraception service as a strategy to improve contraceptive choice and access within Lambeth and Southwark.

Chapter 3 uses elements of Bourdieu's Theory of Practice, including the concepts of capital, habitus and field, to generate an overarching theoretical framework with which to consider contraceptive decision-making and activities as a unique practice. Contraceptive practice is presented as the product of habitus, which is an acquired system of dispositions reflecting past experiences, traditions and habits that engenders homogeneity in outcomes within social groups and is relationally bound with capital and field. The framework is used to consider the interplay of agency and structure in contraceptive practice, the power dynamics in patient-provider interactions, contraceptive health inequalities and the literature on remote and digital contraceptive interventions. Through the Bourdieusian lens, the online service is seen as a new field of access which could attract users of a different habitus to users of existing, face-to-face services, altering capital exchange between patient and provider, such as the knowledge of how to effectively use a method. In addition, Bourdieu's epistemological approach, which encompasses both the subjective and objective, is presented as the research paradigm through which to assess the mixed methods empirical approach of the thesis.

This bulk of this thesis is comprised of four studies (Chapters 4, 5, 6 and 7) presenting evidence to achieve the aims and objectives outlined above. These studies are presented in extended, paper-style reports thus the structure of each chapter is similar to a research paper, but unlike a typical research paper, the length facilitates the presentation of greater detail for each section. The mixed methods employed have involved a range of data sources and analytical approaches justifying distinct chapters that consider the specifics relevant to each study. Furthermore, the intervention is a novel service, offering access to contraception in ways not yet addressed in the literature. Consequently, the first two studies are exploratory in nature, providing results that have helped to shape the research questions and methods in the subsequent chapters.

Chapter 4 presents the first empirical study of the thesis; using qualitative methodology, informed by the literature on theory-driven evaluation (TDE), to generate a conceptual model, or Theory of Change (ToC), for online contraception. The analysis describes stakeholders' perspectives regarding the processes through which an online contraceptive service could improve access to contraception and decrease unplanned pregnancy. Assumptions underpinning these processes are surfaced and interrogated to understand stakeholder predictions around the potential benefits and risks of the online service.

Stakeholder assumptions in Chapter 4 are centred on predictions about the characteristics that could encourage or inhibit effective use of the online service. Therefore, Chapter 5 seeks to test these by describing the characteristics of those who used the online contraception service during its first 15 months of availability using SH:24's routinely collected data. Also identified are the factors associated with repeat use of the online contraception service during this period. The findings generate further empirical questions for the cohort study presented in Chapters 6 and 7.

The Contraception in Person, Contraception Online (CiP-CO) Study is a multi-site, cohort study designed to examine how measures of short-term OCP continuation are associated with type of contraceptive service access among a population of new OCP users. It compares outcomes between participants who used the online service for their first OCP prescription to those who used other services, namely community clinics and general practice, for their first prescription, using both routinely collected service-use data and self-reported data via online questionnaires. In addition to outcomes about short term continuation, Chapter 6 looks at patterns of service-use within and between online and face-to-face services and the reasons for continued use, altered use or termination of use, which, in addition to the exploratory studies, facilitates greater understanding of the impact of online contraception.

Chapter 7 is the second part of the CiP-CO study. Whilst the first part focuses on the results of the cohort study concerning continuation, the second part takes a process evaluation approach. It considers the nascent online contraception service in terms of participants' feedback about their service-use experience and their responses to a series of questions in the online questionnaire to determine their basic knowledge of OCPs and compares outcomes to participants using other services for their first supply of OCPs.

The final chapter of this thesis presents a critical discussion of the findings of the research. It discusses the strengths and limitations of the research in relation to the theoretical framework and the theory of change conceptual model. This chapter draws together the results to discuss implications for the future of online contraception within the current context of

contraceptive provision and makes recommendations for the direction of research on online contraception and related fields.

2 Background

2.1 Chapter Overview

This chapter states the rationale for the research in this thesis in terms of the issue of unplanned pregnancy and its adverse effects. It presents the national data on rates of unplanned pregnancy and how these have been affected by shifts in the context of contraceptive service provision in recent decades. It contains a review of the literature on remote and digital contraceptive counselling interventions. Background information on the research context sets the scene for the intervention of online contraception that has been commissioned in Lambeth and Southwark, the details for which are also presented in this chapter.

2.2 The Issue of Unplanned Pregnancy

Globally, of the 208 million pregnancies that occurred in 2008, approximately 41% were unintended, which includes 33 million unplanned births, 41 million induced abortions and 11 million miscarriages (50). Unplanned pregnancy is associated with adverse health, economic, social and psychological outcomes for women and children (2). Increased investment and expansion in access to contraception is recommended to prevent unplanned pregnancies and improve reproductive health worldwide (7). However, the most recent figures suggest that 146 million (130 – 166 million) women aged 15 – 49 years who are married or in a union have an unmet need for contraception.

In developed regions, despite contraceptive prevalence being at 71.5% (95% uncertainty interval 67.7-74.8) compared to 54.1% (95% uncertainty interval 50.4-57.5) in developing countries (7), unplanned pregnancies continue to have public health relevance. They disproportionately impact women in lower socioeconomic groups (4, 5) and are particularly common among adolescent and young adult women (51, 52). Adolescent pregnancies and births are associated with the loss of educational opportunities and societal marginalisation (50). The highest adolescent pregnancy rate in high-income countries, excluding the former Soviet Bloc, is in the United States and the highest rates in Western Europe are in England, Wales and Scotland (3). The direct medical costs of unintended pregnancies were over £193 million in England in 2010 (53). Of the 225 600 unintended pregnancies, 155 500 (68.9%) resulted in induced abortions; which constituted the greatest share of the total sum at nearly £143 million. Although the conception rate of 77.5 conceptions per 1000 women aged 15 to 44 years in England and Wales is at its lowest since 2005 (18), unplanned pregnancy is still a highly pertinent issue, affecting the most marginalised and vulnerable. Unplanned pregnancy is associated with lower educational attainment, hard drug use and sexual intercourse before

16 years of age (1). Use of contraception is negatively associated with belonging to an ethnic minority group (8) and living in a more deprived area (54).

2.3 The measurement and meaning of unplanned pregnancy

The definition and measurement of unplanned pregnancy is variable within the literature (55) which can result in methodological setbacks in estimating prevalence and thus hinder the design of preventative interventions (1). Unplanned pregnancies have been defined as those which have occurred through the failure of a contraceptive method or through non-use of contraception for conception where a pregnancy was not actually desired (51). Pregnancies that result in abortion are routinely categorised as unplanned (50), whilst the planning status of pregnancies that occur in live births are commonly assessed using the standard questions that have been developed by large surveys such as the International Demographic and Health Survey (DHS) and the National Survey of Family Growth (NSFG) from the United States (US) (50, 51), which include, “at the time you became pregnant, did you want to become pregnant then, did you want to wait until later, or did you not want to have any more children at all?” (1, 2).

Another frequently used term in the literature is *unintended* pregnancies. The most recent publication on global levels, trends and outcomes included births, induced abortions and miscarriages that resulted from unintended pregnancies and used a combination of United Nations estimates, and estimations from recent trends and models (56). This term has been used interchangeably with pregnancies that are unplanned but has also been given a distinct definition as a related concept referring to all pregnancies that are reported to have been unwanted or mistimed (51). For a pregnancy to be ‘mistimed’, it must occur earlier than desired. For a pregnancy to be ‘unwanted’ the individual must have no desire to have any or more children at all (51).

There are two central concerns with these definitions: firstly they assume that individual cognitive control results in a conscious decision on pregnancy made at the time of pregnancy or before its occurrence (57); secondly, measurements have used estimates derived from dichotomous questions that fail to capture the nuances of pregnancy intentions. Furthermore, unintended pregnancy is usually based on retrospective self-reporting, so in cases where pregnancy resulted in birth, may be strongly influenced by the presence of a baby (58). The characterisation of a pregnancy as unintended or unplanned can also vary between individuals and across social and cultural environments and temporal periods making it problematic to cross-compare studies from different settings (55). The validity of grouping both timing and wantedness in the classification has also been questioned because there are differences in their precursors and their outcomes when the two reasons are separated for analysis (51, 59).

More sophisticated tools that use multi-item measures to place planning status along a continuum (60-62) have been developed to address some of these concerns. The third National Survey of Sexual Attitudes and Lifestyles (NATSAL-3), which will be discussed further in section 2.4.1, uses the psychometrically validated London Measure of Unplanned Pregnancy (LMUP) (63-65). This measure was developed through qualitative interviews with pregnant or recently pregnant women from a range of UK service providers (from abortion clinics to general practice) to produce a conceptual model of pregnancy planning (Figure 2-1) (63). From this, items were pre-tested, field tested and psychometrically tested to demonstrate the high reliability (Cronbach's a=0.92; test-retest reliability=0.97) and high face, content and construct validity. The measure allows for the expression of mixed feelings about pregnancy through scoring six questions asking about use of contraception, timing of parenthood, pregnancy intention, desire for a baby, discussion with a partner and pre-conceptual preparation. Through this they were able to categorise pregnancies as not just either planned or unplanned, but also ambivalent - adding to the increasing recognition of the mixed feelings it is possible to have towards pregnancy (66). In recognition of the reliability, validity and contemporaneousness of this measure, this thesis will herein refer to unplanned pregnancies as the ultimate public health outcome of ineffective use or non-use of contraception.

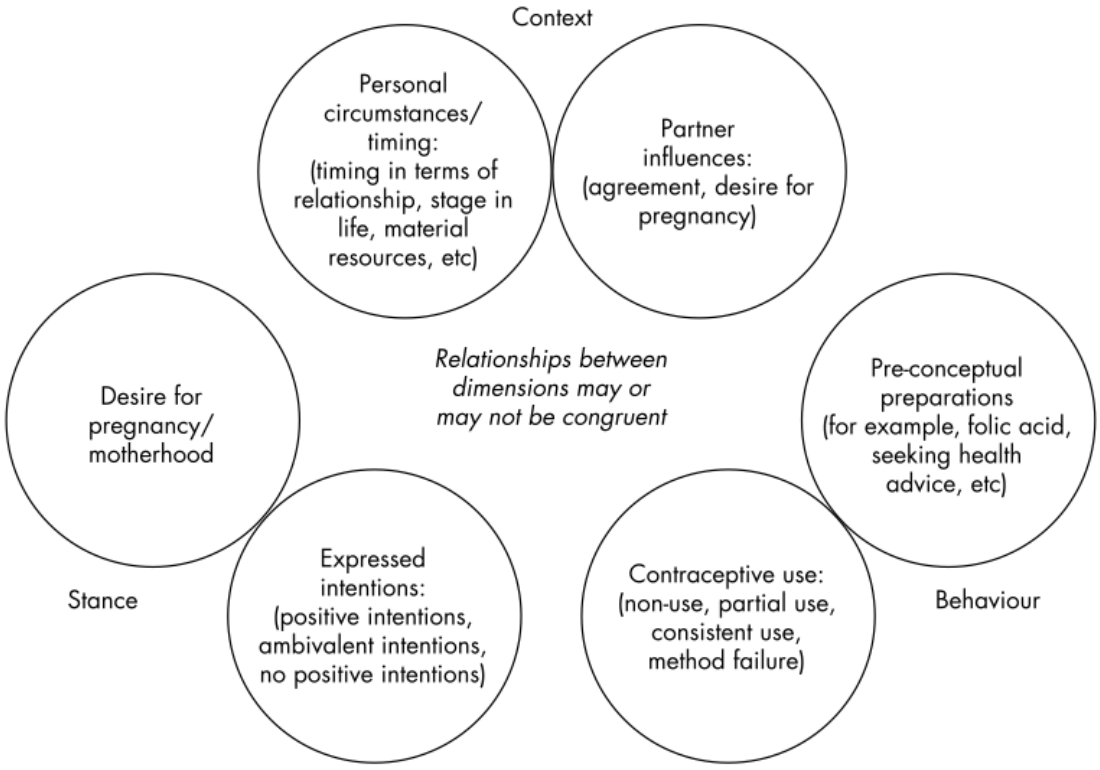


Figure 2-1 Conceptual Model of Pregnancy Planning/Unplanned Pregnancy (Barrett, 2004)

2.4 Unplanned pregnancy in the United Kingdom (UK)

Data on unplanned pregnancy in the UK is fragmented across studies from different years and populations.

2.4.1 National Surveys of Sexual Attitudes and Lifestyles (NATSAL)

Much of the current body of research on national reproductive and contraceptive behaviour has been generated from The British (England, Scotland and Wales) National Surveys of Sexual Attitudes and Lifestyles (NATSAL) which have been conducted three times since 1990 with the latest, NATSAL-3, sampling 15 162 adults aged 16 – 74 years in 2010-2012 (67). Measuring unplanned pregnancy was not included in the previous iterations of the survey but was added to NATSAL-3 in addition to other questions that could affect sexual lifestyles (68).

According to Wellings et al. (2013), the NATSAL-3 data gives an annual prevalence estimate for unplanned pregnancy, using the LMUP, of 1.5% (95% Confidence Interval [CI] 1.2 – 1.9) (1). Authors approximate that one in six of the pregnancies taking place in the year prior to interview were unplanned and between a quarter and a third were ambivalent. It was more common for women aged 16–19 years to report their pregnancies as unplanned (45·2% [95% CI 30·8–60·5]) although most of the unplanned pregnancies that occurred were in women aged 20–34 years (62·4% [95% CI 50·2–73·2]). The study identified several factors that were associated with unplanned pregnancy, including, current smoking (2·47 [95% CI 1·46–4·18]), recent use of drugs (3·41 [95% CI 1·64–7·11]), and lower educational attainment.

The central limitation of the NATSAL-3 data is that it is reliant on self-reported data, requiring participants to reflect on circumstances surrounding contraceptive activity and pregnancy in the previous year, the latter of which is particularly likely to be influenced by after-the-fact rationalisation (1, 62). Nevertheless, its population-wide, stratified, probability sample and use of the LMUP make it the most useful research for estimating national unplanned pregnancy.

2.4.2 Abortion Rates

The Department of Health and Social Care publish annual summary information from the abortion notification forms returned to the Chief Medical Officers (CMOs) of England and Wales (48) . There were 192 900 abortions for women resident in England and Wales (48). The age standardised abortion rate was 16.7 per 1000 women aged 15-44 years. Women aged 20-24 years had the highest abortion rate at 28.2 per 1000 women. The latest data from Scotland indicates that there were 12 063 abortions in 2016 at a rate of 11.6 per 1000 women aged 15-44 years (69). In Northern Ireland, abortion is illegal except for in cases where it is evident that the life of the mother is at serious risk. There is no official data on the prevalence

of illegal abortions here, but statistics from England and Wales in 2017 indicate that 919 women from Northern Ireland had abortions as non-residents (48).

Figure 2-2 is the age standardised abortion rate per 1000 women aged 15-44 years over time showing that by 2017, the rate of 16.7 per 1000 had more than tripled relative to the rate of 5.1 per 1000 recorded in 1969. There has also been an increase since the 2016 rate of 16.0 per 1000 resident women aged 15-44 years.

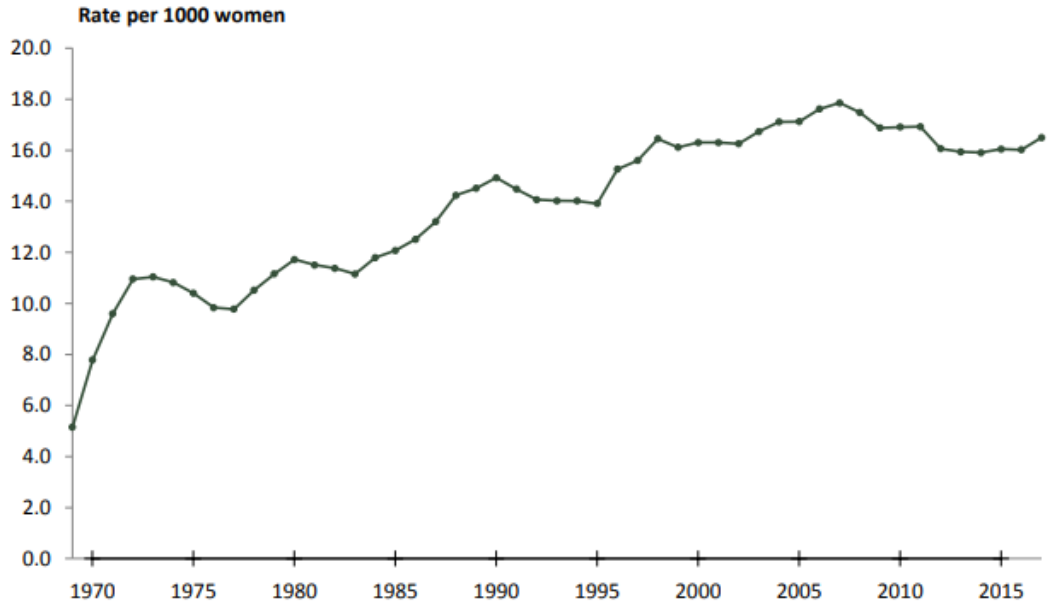


Figure 2-2 Age Standardised Abortion Rate per 1000 Women aged 15-44 years, England and Wales, 1969 – 2017 (Department of Health & Social Care and National Statistics, 2018)

The Office for National Statistics (ONS) report annual statistics on conceptions to residents of England and Wales. From 1996 to 2016, the proportion of conceptions leading to abortion increased for women aged under 30 years, decreased for women aged 35 and over and remained comparatively stable for women aged 30 to 34 years (18). There was an increase in the percentage of conceptions leading to a legal abortion from 2015 to 2016 for women in all age groups, except for those aged 40 years and over.

2.4.3 Adolescent Pregnancy

The under-18 conception rate in 2016 was 18.9 conceptions per 1000 women aged 15 to 17 years which is the lowest rate recorded since 1969 and a 10% decrease from the year before (18). The estimated number of conceptions to women aged under 16 years in 2016 reduced by 19% from the previous year, from to 3466 in 2015 to 2821 in 2016. The reasons for this decline will be discussed further within section 2.7. It should also be noted that there is variation in the under-18 conception rates according to region and local authority (Figure 2-3).

The under 18 abortion rate is 8.2 per 1000 resident women in England and Wales (48) and in Scotland the rate is 14.6 per 1000 women aged 16-19 and 1.5 per 1000 women aged 13-15 years (69). The proportion of conceptions in England and Wales leading to abortion are higher among younger age groups (48). The proportion of conceptions leading to abortion was 51.4% in 2016 for women under 20, up from 48.4% in 2006. The proportion of conceptions leading to abortion was 61.5% in 2016 for women under 18 years, up from 59.8% in 2006.

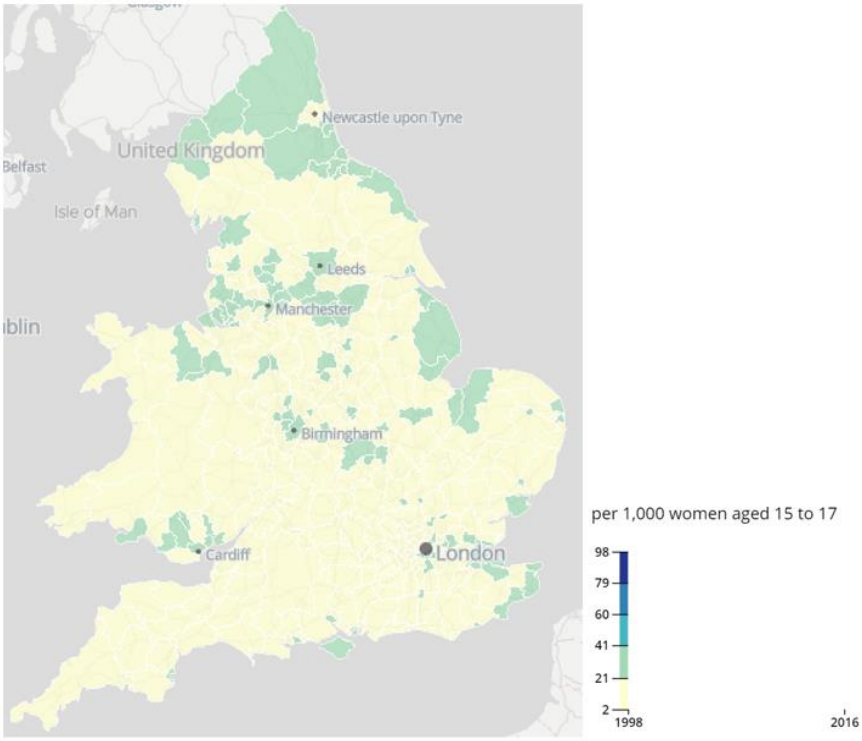


Figure 2-3 Under-18 Conception Rates by Local Authority, 2016, (Office for National Statistics, 2018)

2.4.4 Overview of the Data on Unplanned Pregnancy in the UK

There has been a substantial decline in conception rates among adolescent women, although there remains some concern over the enduring disparities across regions and local authorities (Figure 2-3). In addition, despite the overall decline in conception rates across age groups, the NATSAL-3 data suggests that one in six pregnancies are unplanned and national abortion data shows that abortion rates are continuing to increase (1, 48). Whilst this incline could be interpreted to mean that women are experiencing increasingly effective access to abortion services, it is also an indicator that there may be barriers to access and effective use of the contraceptive services that could be preventative of this outcome.

2.5 Contraception

Women in Britain now spend, on average, around 30 years of life during which they wish to avoid pregnancy (1). Over this time period, it is considered essential that they have access to a range of contraceptive method options (6). According to NATSAL-3 data, the majority of

women aged 16-44 years reporting having vaginal sex self-reported accessing at least one source of contraceptive supplies in the previous year (87%) (70). Contraceptive method options include Long - Acting Reversible Contraception (LARC) that require administration less than once per month, short-acting methods that require the user remembering to take or use them regularly including the oral contraceptive pill (OCP), barrier methods, methods that are behavioural such as withdrawal or Lactational Amenorrhoea Method (LAM) and methods that are permanent. Figure 2-4 is an image from “Family Planning: a Global Handbook for Providers” produced by the World Health Organization (WHO) in which contraceptive or “family planning” methods are arranged by order of effectiveness (71).

The term “effectiveness” is a measure of the extent to which a method is preventative of pregnancy under clinical trial conditions and can also be described as “perfect use failure rate” (72). The term “efficacy” measures the ability of a method to prevent pregnancy when used under non-trial conditions, where issues such as compliance to dose regimen are likely to be impactful. This can be described in terms of “typical use failure rate”. Clinical trials also report failure rates using The Pearl Index, which is the number of contraceptive failures per 100 women-years of use. Alternatively, trials can use Life Table Analysis which describes the contraceptive failure rate per month of use which is useful in showing the cumulative failure rate over a specific period of time.

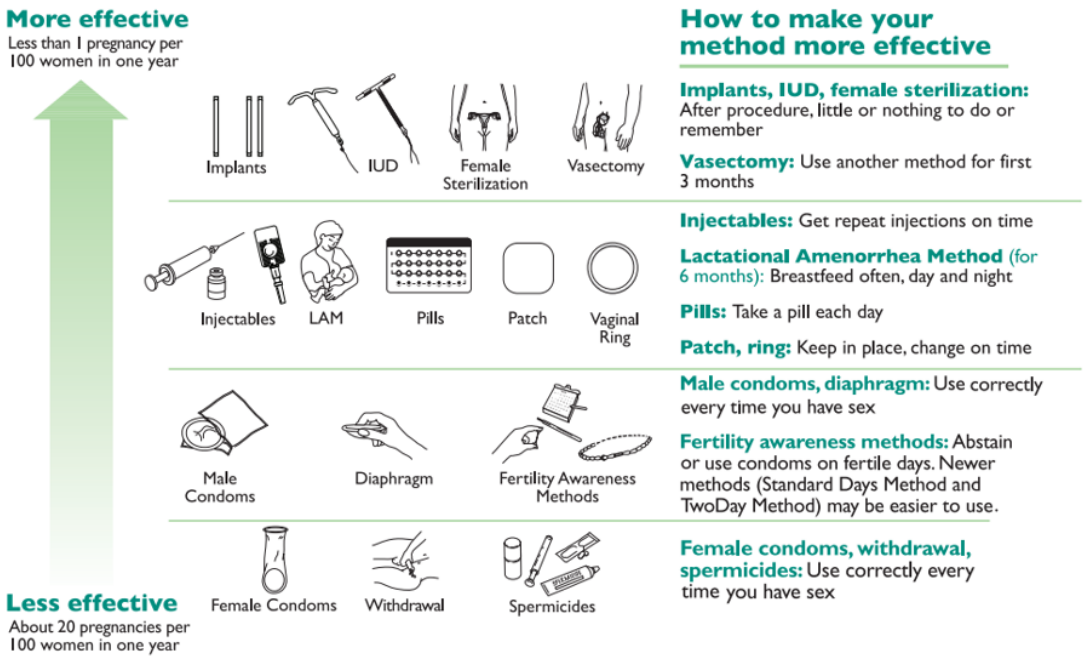


Figure 2-4 Comparing Effectiveness of Family Planning Methods (USAID, Johns Hopkins Bloomberg School of Public Health, Johns Hopkins Centre for Communication Programmes, World Health Organization, 2018)

Intrauterine device, IUD

2.5.1 Oral Contraceptive Pills (OCPs)

There are a variety of brands of OCPs, all differing in their hormonal content but broadly categorised as either combined oral contraceptive pills (COCs) or progesterone-only pills (POPs). The Health Improvement Network (THIN) is a large UK general practice database, analysis of which placed the prevalence for COCs at 16.2% (95% CI 16.1–16.3%) and 5.6% (95% CI 5.5–5.6%) for POPs among 194 054 female, GP attendees aged 12- 49 years in 2008 (73). The latest analysis of SRH service data (2016-17), estimated the prevalence of OCP use at 44% (74).

OCPs are prone to what is termed “user-error”, primarily through women missing pills (75, 76) or not renewing supplies (29, 76-78). Missing pills and discontinuation put women who remain sexually active at high risk of unplanned pregnancy (79). Further analysis of the THIN data found that among the COC users, 9.8% switched to an alternative brand, 9.0% switched to a different method, and among those who did not switch, 34.8% discontinued at or prior to 3 months and 50.1% discontinued by 6 months (73). Among the POP users, discontinuation was similar, with 38.2% doing so by 3 months and 49.7% discontinuing by 6 months.

Perceptions or experiences of side effects are often cited as key contributors to women’s decisions about OCP discontinuation and inconsistent use (79-82). Guidelines contain the advice that “women should be informed thoroughly about all potential side effects when starting contraception” in addition to information about non-contraceptive health benefits and risks associated with use (83). It is common for women to cite altered bleeding patterns as the reason for discontinuing POPs (84-86) so guidelines stress the importance of providing information about this particular side effect (87) as evidence suggests that this can reduce discontinuation (88).

2.5.2 Long-Acting Reversible Contraception (LARC)

LARC methods are copper intrauterine devices (Cu-IUDs), progestogen-only intrauterine systems (IUSs), progestogen-only injectable contraceptives and progestogen-only subdermal implants; key information for these are summarised in Table 2-1. LARCs are reported to be highly cost-effective and have typically been associated with lower failure rates than methods that require the user remembering to take or use them (89) and as such, support for their increased uptake was contained within the 2005 National Institute for Health and Care Excellence (NICE) guidelines (last updated September 2014) (90). These guidelines state that “women should be given information about and offered a choice of all methods, including LARC methods”. Increased LARC uptake in England has been significantly associated with a reduction in rates of conception and abortion among women under 20 years (19). However, LARC methods remain relatively under-utilised, particularly among younger age groups (74,

91, 92). In addition, despite their long-term effectiveness, studies show that many women have their LARC methods removed prior to the end of their duration of use (92-94).

A study of 324 women choosing progestogen-only implants in a community clinic in Scotland found that continuation rates were 89% (for the 85% of participants who could be followed up) (94). Among the 68 women who discontinued within 1 year, 62 (91%) did so because of side effects, the most commonly cited side effect being frequent and/or unpredictable bleeding (62%). This is supported by other studies associating implant discontinuation with dissatisfaction with bleeding (95, 96). It is recommended that the likely impact on bleeding patterns (outlined in Table 2-1) are highlighted during contraceptive counselling.

Walker and colleagues examined the barriers to uptake of intra-uterine contraception (IUC) by women in general practices across the UK (91). They utilised findings from 30 qualitative interviews to develop a survey tool which was distributed to 1195 women of reproductive age. The strongest predictors of non-use were an adverse opinion regarding the long-term nature of IUC (odds ratio, OR = 8.34), a negative opinion about the prospect of having IUC inside the body (OR = 3.14) and concerns about the effect of IUC on future fertility (OR = 2.59). In the light of these potential barriers to IUC uptake, authors recommended that clinicians provide information about the possibility of early removal of IUC and highlighted the importance of seeking to alleviate concerns about safety and side effects.

Table 2-1 Summary of Long-Acting Reversible Contraception (LARC) Available in the UK (Adapted from NICE, 2005, last updated 2014)

	Copper intrauterine devices (Cu-IUDs)	**Progestogen-only intrauterine systems (IUSs)**	**Progestogen-only injectable contraceptives**	**Progestogen-only subdermal implant**
Description	Small, T-shaped plastic and copper device. The copper is released into the uterus; alters cervical mucus inhibiting fertilisation and implantation.	Small, T-shaped plastic device which releases progestogen into the uterus inhibiting fertilisation and implantation and can prevent ovulation.	Releases progestogen into the bloodstream to prevent ovulation. Also inhibits fertilisation and implantation.	Small, flexible, plastic rod. Primarily works by preventing ovulation but also inhibits fertilisation and implantation.
Insertion	Fitted by a trained healthcare professional through the cervix and into the uterus (97).	Fitted by a trained healthcare professional through the cervix and into the uterus (97).	Injections by a trained healthcare professional usually in the gluteal or deltoid muscle or the lateral thigh and less commonly, the upper arm (97). Sayana Press injection can also be in the abdomen or thigh and can be done by the woman herself at home.	Inserted into the upper arm by a trained healthcare professional (97).

	Copper intrauterine devices (Cu-IUDs)	Progestogen-only intrauterine systems (IUSs)	Progestogen-only injectable contraceptives	Progestogen-only subdermal implant
Duration of use	5 - 10 years for Cu-IUDs with 380mm^2 copper, depending on type. Or until contraception no longer needed if woman 40 years or more at time of insertion.	Mirena IUS - 5 years. Jaydess IUS – 3 years. Until contraception no longer needed if woman 45 years or more at time of insertion and does not have periods with IUS in place.	DPMA is the most commonly used and lasts for 13 weeks. NET-EN requires repeat injections every 8 weeks. Sayana Press lasts for 13 weeks but is not so widely available.	3 years.
Failure rate	Fewer than 2 in 100 women over 5 years, for Cu-IUDs with at least 380mm^2 copper. Expulsion occurs in fewer than 1 in 20 women in 5 years.	Fewer than 1 in 100 women over 5 years. Expulsion occurs in fewer than 1 in 20 women in 5 years.	Fewer than 0.4 in 100 over 2 years; pregnancy rates lower for DPMA than NET-EN. FPA states that "with perfect use, over 99% effective; fewer than 1 in 100 injection users will get pregnant in a year. With typical use, around 94% effective; around 6 in 100 injection users will get pregnant in a year".	Fewer than 1 pregnancy in 1000 implants fitted over 3 years.
Prevalence	4.5% (95% CI 4.4-4.5%) among GP attendees aged 12- 49 years in 2008 using data from THIN (73). 6% attendees of SRH services 2016-17 (74).	4.2% (95% CI 4.1-4.2%) among GP attendees aged 12-49 years in 2008 using data from THIN (73). 8% attendees of SRH services 2016-17 (74).	2.4% (95% CI 2.3–2.4%) among GP attendees aged 12- 49 years in 2008 using data from THIN (73). 9% attendees of SRH services 2016-17 (74).	1.5% (95% CI 1.5–1.6%) among GP attendees aged 12-49 years in 2008 using data from THIN (73). 15% attendees of SRH services 2016-17 (74).
Discontinuation	7.5% among GP attendees aged 12- 49 years using THIN data 2004-2009 (93). NICE guidelines state that up to 50% of women stop using Cu-IUDs within 5 years.	10.6% among GP attendees aged 12-49 years using THIN data 2004-2009 (93). NICE guidelines state that up to 60% of women stop using IUS within 5 years.	54.4% among GP attendees aged 12- 49 years using THIN data 2004-2009 (93). NICE guidelines state that up to 50% of women stop using DMPA by 1 year.	13.2% among GP attendees aged 12-49 years using THIN data 2004-2009 (93).
Counselling Guidelines	In addition to information on insertion procedure and failure rate, key features of Cu-IUDs to discuss are: - Effect on periods: heavier bleeding and/or dysmenorrhea (painful periods) likely - Risk of ectopic pregnancy should	In addition to information on insertion and failure rate, key features of IUSs to discuss are: - Irregular bleeding and spotting common in first 6 months - Oligomenorrhoea (infrequent periods) or amenorrhoea (absence of periods) likely by end of first year	In addition to information on procedure and failure rate, key features of progestogen-only injections to discuss are: - Amenorrhoea common, and is more likely with DMPA than NET-EN, and with longer use; not harmful - Persistent bleeding may occur	In addition to information on insertion procedure and failure rate, key features of implant to discuss are: - Bleeding patterns are likely to change during implant use. Bleeding may stop, become more or less frequent, or be prolonged. Dysmenorrhoea may be reduced.

	Copper intrauterine devices (Cu-IUDs)	Progestogen-only intrauterine systems (IUSs)	Progestogen-only injectable contraceptives	Progestogen-only subdermal implant
	woman become pregnant with Cu-IUD in situ - Most common reasons for discontinuation are unacceptable vaginal bleeding and pain - Pelvic inflammatory disease: less than 1% for women at low risk of STI - Uterine perforation: less than 1 in 1000 - Change in mood or libido: may be a small effect - No evidence of effect on weight gain or fertility delay post removal.	- Risk of ectopic pregnancy should woman become pregnant with IUD in situ - Most common reasons for discontinuation are unacceptable vaginal bleeding and pain, less common reason is hormonal (non-bleeding) problems - Pelvic inflammatory disease: less than 1% for women at low risk of STI - Uterine perforation: less than 1 in 1000 - Change in mood or libido: may be a small effect - Acne risk may increase - No evidence of effect on weight gain or fertility delay post removal.	- Most common reason for discontinuation is an altered bleeding pattern - Weight gain: may be up to 2–3 kg over a year on DMPA - Bone mineral density: DMPA use is associated with small loss; largely recovered when DMPA is stopped - Can take up to 1 year for fertility rate to return to normal once method stopped.	- Complications with insertion and removal are uncommon. - No evidence of a delay in fertility.

THIN, The Health Improvement Network; NICE, National Institute for Health and Care Excellence; SRH Sexual and Reproductive Health; DPMA Depo-Provera; NET-EN Noristerat; GP General Practice; STI sexually transmitted infection; IUS Intrauterine system; Cu-IUD copper intrauterine device

2.5.3 Other Short-Acting Methods: Vaginal Ring and Contraceptive Patch

The most effective, non-barrier short-acting methods include the vaginal ring, the contraceptive patch and the OCP (Figure 2-4). Short-acting methods require the user remembering to take, use or replace them either daily, weekly or monthly. Therefore, whilst their theoretical effectiveness is high, their actual effectiveness is diminished relative to LARC methods (see section 2.5.2) (98). They release fertility-interrupting hormones with the main difference between the methods being their mode and frequency of application or intake. The vaginal ring is placed by the user into the vagina where it remains for 21 days, then it is removed for a 7-day break, at the end of which a new ring is inserted (99). The contraceptive patch is stuck to the skin where it remains effective for 7 days, after which it is replaced with a fresh patch, with a 7-day patch-free break every 21 days. In contrast, OCPs must be taken daily, although some types also include a 7-day pill-free break (see section 2.5.1) (100, 101).

A recent Cochrane review compared the effectiveness, compliance and related outcomes between the patch, ring and COCs (102). It reported that contraceptive effectiveness was not

statistically significantly different across the three method types with a failure rate of 0.3 per 100 women per year with perfect use and 8 with typical use. Compliance was improved in the patch users compared to the COC users although they had more side effects and were more likely to discontinue early. Ring users reported few adverse events and were less likely to discontinue compared to COC users. Ascertaining the prevalence of patch and ring use in the UK is challenging as recent research has categorised these under the general heading of hormonal methods (103) and they were not mentioned in the latest statistics on SRH services in England (74).

2.5.4 Methods that Rely on Behaviour Alone

Methods that are dependent on behaviour rather than specific devices or supplies include withdrawal, fertility awareness-based (FAB) methods, abstinence and lactational amenorrhoea method (LAM) (Figure 2-4).

LAM is only possible during the first 6 months after a woman gives birth, provided she is experiencing complete amenorrhoea and the baby is getting at least 85% of its feeds from the mother's breast milk (104). Its mechanism of action is not fully understood but is believed to be related to altered gonadotrophin release which delays the return of ovulation. Although only an option during a specific set of circumstances, it is relatively effective, with 0.5% of women conceiving due to method failure if used perfectly in the 6 months following childbirth; raised to 2% when used typically.

FAB methods of contraception are described by WHO, 2000 as involving the "identification of the fertile days of the menstrual cycle, whether by observing fertility signs such as cervical secretions and basal body temperature, or by monitoring cycle days. FAB methods can be used in combination with abstinence or barrier methods during the fertile time" (105). A systematic review for these methods from 2004 concluded that there is limited quality data available to establish reliable estimates for their relative efficacy (106). Certain conditions can make these methods complex such as menstrual irregularities. In recent years there has been a proliferation in mobile phone applications (apps) to facilitate the tracking of fertility biomarkers. Some studies have cautioned against relying solely on apps for pregnancy prevention (107) and stressed the variability in the quality of the various options available (108). FAB apps reportedly have a typical-use failure rate of 8.3% (95% CI: 7.8-8.9) estimated over 13 cycles and a method failure rate (which Scherwitzl et al. (2017) describe as an equivalent measure to perfect-use failure rate) of 0.5 pregnancies (95% CI: 0.4-0.7) per 100 woman-years (109). The study which determined these rates has been criticised for contravening the requirements of Phase 3 efficacy studies casting down on the accuracy of these failure rate calculations (110). Scherwitzl et al. (2017) appear to have included women aged 35 years and over and those with irregular menstrual cycles in their failure rate calculations. Furthermore, they have included cycle data with inadequate reporting of the

intercourse that has taken place during that cycle (reported in only 32% of cycles rather than the required documentation of intercourse at least once per cycle for that cycle to be included in efficacy calculations).

Withdrawal is a behavioural method that takes place at the time of vaginal, sexual intercourse whereby the male withdraws or “pulls out” before ejaculation (111). Estimates of perfect use suggest that 4% of couples would become pregnant over the period of a year, rising to 18% for typical use (112). Whilst effectiveness is poor relative to LARC and other hormonal methods, it is only 1% higher than the failure rate estimate of typical use for male condoms (17%). Studies suggest that withdrawal is often used in conjunction with other methods or to compensate for irregular condom use (113-115). A US study using data from the 2006-2010 NSFG found that sexually active people aged 15-24 years who had more positive attitudes toward pregnancy were 2.2 – 2.6 times as likely to use withdrawal than those who said they would be upset if they became pregnant (116). Withdrawal was also associated with the opinion that condoms diminished sexual pleasure.

2.5.5 Barrier Methods

Barrier methods are non-hormonal contraceptives and include male and female condoms and the diaphragm. Male condoms (worn on the penis) and female condoms (worn inside the vagina) are the only contraceptive methods that offer protection against the transmission of HIV and sexually transmitted infections (STIs) in addition to pregnancy prevention (117). The proportion of women experiencing pregnancy within the first year of typical use is 18% and 21% for male and female condoms respectively, compared to a perfect-use failure rate of 2% and 5% (118). The relatively high typical-use failure rate is a consequence of inconsistent or incorrect use. Analysis of NATSAL-3 data found that women at risk of pregnancy commonly used barrier methods (16.4%), particularly younger participants and those in short-term relationships (103). Unlike other contraceptives, condoms are often purchased from retail outlets, with NATSAL-3 data indicating that 54.6% of men accessed these for their contraceptive supplies (70).

A diaphragm is a silicone dome that covers the cervix, used in combination with spermicide to prevent entry of the sperm into the uterus for egg fertilisation (119). It must be inserted prior to sexual intercourse and left in place for a minimum of 6 hours after sex. The diaphragm has a 12% typical-use failure rate and a 6% perfect-use failure rate (120). It is considered particularly suitable for women aged over 35 years as they may be more likely to show compliance and their fertility is likely to have diminished (121). Ascertaining the prevalence of diaphragm use in the UK is challenging as recent research has categorised these under barrier methods along with condoms (103) and they were not mentioned in the latest statistics on SRH services in England (74), which in itself may indicate limited uptake of the method

from these services. Research from the US NSFG suggests a steep decline in popularity of the device, perhaps related to the complexity of user guidelines and preferences for alternative barrier or hormonal methods (122).

2.5.6 Permanent Methods: Sterilisation and Vasectomy

Permanent methods of contraception are among the most effective methods available (Figure 2-4). Female sterilisation, or tubal occlusion, involves the severing or sealing of the fallopian tubes, thus preventing the transition of the egg from ovaries to uterus (123). Male sterilisation or vasectomy involves the cutting, sealing or tying of the vans deferens, thus preventing the movement of sperm from the testicles to the penis (124).

There were 12 007 vasectomies reported in NHS hospitals in England in 2017/18 (74). This was around a 10% increase from 2015/2016 although still only half of the number recorded in 2007/2008. Whilst female sterilisation remains the most commonly used contraceptive globally (125), the method has rapidly declined in popularity in England, with 13 723 performed in NHS hospitals in 2017/2018, a decrease of 31% over 10 years (74). This may be related to falling conception rates among younger age groups or due to a growing preference for LARC methods, many of which are equally as effective as sterilisation as shown in Figure 2-4.

2.5.7 Emergency Contraception (EC)

Methods which are not listed in Figure 2-4 are forms of emergency contraception (EC). These are important to include in a discussion of contraceptive choices as the only effective methods that can be used after unprotected sexual intercourse (UPSI) or sexual assault or to compensate for the failure of other forms of contraception such as missed OCPs or condom breakage.

There are three EC methods that can be used in the UK: Levonorgestrel (LNG); Ulipristal acetate (UPA); and the Cu-IUD all of which are summarised in Table 2-2. Despite the body of evidence indicating EC is a valuable and effective approach to pregnancy prevention for the individual, studies report that increasing access to hormonal EC does not reduce overall pregnancy rates (127, 128) or abortion rates (129, 130) or unplanned pregnancy rates on a population level (131). Non-use of EC is often related to failure to recognise the risk of pregnancy (132), the neglect of perceived risk (133), inconvenience and fear of side-effects (134). Qualitative studies interviewing young women from urban areas also report stigma, personal difficulties in asking for EC, negative experiences with healthcare professionals and misperceptions about the method as further barriers to EC (135, 136). It may be that the current configuration of EC services are not meeting the needs of all women (137) and that

interventions that have sought to increase access have not targeted those most at risk (138, 139).

Table 2-2 Summary of Methods of Emergency Contraception in The UK (Adapted from Faculty of Sexual & Reproductive Healthcare Clinical Effectiveness Unit, Guidance Emergency Contraception, 2017)

Emergency Contraception (EC)	Mechanism of action	Licensed Time Frame	Advantages	Disadvantages
Levonorgestrel (LNG)	A progestogen hormone that prevents follicular rupture and ovulation	Within 3 days post unprotected intercourse (UPSI) or contraceptive failure	1. Easily accessible from a range of providers 2. No medical contraindications 3. Can be used more than once in the same cycle	1. Ineffective once the luteal hormone has started to rise 2. Subject to the inaccuracies of self-reported cycle information (140) 3. Possible minor side-effects, e.g. headache, nausea and altered bleeding patterns
Ulipristal acetate (UPA)	A progesterone receptor modulator that prevents follicular rupture and ovulation	Within 5 days post UPSI or contraceptive failure	1. Can be used until just after the rise in luteal hormone so the window of opportunity for pregnancy prevention is extended (141, 142) 2. Limited accessibility as all products are prescription only medication	1. Medical contraindications include pregnancy and severe uncontrolled asthma 2. Possible interaction between UPA and progestogen-containing contraception 3. Not advisable to use UPA with liver enzyme-inducing drugs. 4. Possible minor side-effects, e.g. headache, nausea and altered bleeding patterns
Copper-bearing intrauterine device (Cu-IUD)	Prevents fertilisation and effects the uterine fluid and endometrium (143)	Within 5 days post first UPSI in a cycle or within 5 days from the earliest estimated date of ovulation	1. Can provide regular, effective contraception for up to 10 years 2. Highly effective to prevent pregnancy even post-ovulation	1. Requires an invasive procedure by a trained healthcare professional 2. Contraindications include untreated sexually transmitted infections or pelvic infections 3. Possible complications once fitted, e.g. rejection by the womb 4. Possible side-effects if used as contraception e.g. vaginal bleeding and pain

2.5.8 Overview of Contraceptive Methods

Comparing the contraceptive methods described here emphasises the importance of offering women multiple options to suit their needs, circumstances and lifestyles. Each method has advantages and disadvantages with several of the observational studies mentioned highlighting perceptions and experiences of side-effects as a critical factor in inhibiting uptake and motivating discontinuation; prompting recommendations for prioritising the discussion of side-effects during the consultation process.

Wellings et al. (2015) analysed the survey responses of 893 potentially fertile women aged 18 – 49 years in 2008 to explore patterns of contraceptive choices in England (145). They found that discontinuation or method switching were due to reasons of ease of use, reliability, side effects or concerns over adverse health effects with the authors stating that "for the most part, this was their personal decision" rather than being influenced by their health providers. This conclusion is judged to be flawed due to the mutually dependent nature of the patient-provider interaction as explained above. For example, should a participant self-report her reasons for discontinuation due to side-effects, she may not be consciously aware of the role that the consultation with the provider played in alleviating, exacerbating or preserving her existing beliefs. Other studies corroborate that providers are highly influential in terms of patients' method choices (146, 147) and effective use of contraception (148-150).

There appears to be an important interplay between the personal perceptions of service-users and the provider role in conveying information to guide contraceptive decision-making. This will be explored further in Chapter 3. Furthermore, perceptions and experiences of side effects are just some of the complex array of factors at play. The reasons for the variation in uptake and effective use of contraception across the population of reproductive age is also associated with underlying sociodemographic and socioeconomic factors.

2.6 Factors Associated with use of Contraception

The study from Wellings et al. (2015) exploring patterns of contraceptive choices in England also studied the factors associated with contraceptive non-use and discontinuation among their sample of 893 reproductive-aged women (145). They found that 65.5% had used the same contraceptive method continuously throughout the 12-month study period. Among those at risk of unplanned pregnancy, 4.7% were non-users of contraception, which, compared to continuous users, was associated with not having educational qualifications, being economically inactive and smoking and drinking. The 3.7% who discontinued and/or changed their method were compared to the continuous users and were more likely to be younger, single and better educated. This latter factor is an interesting finding when considering that lower levels of education are usually associated with poorer reproductive health outcomes including unplanned pregnancy (151). This may be a consequence of the

inclusion of the 107 ‘switchers’ or women who had transitioned from one method to another perhaps due to higher levels of education enabling them to explore the various contraceptive options.

In addition to determining factors associated with unplanned pregnancy, Wellings et al. (2013) analysed NATSAL-3 data to determine changes in the prevalence of pregnancy, intention and contraceptive use, shown in Figure 2-5 (1). The authors do not provide a working definition of “effective” and “less effective” in the study, only stating that less effective methods included EC, thus limiting the interpretation of these findings. However, it could be assumed that effective methods included oral/injectable methods, LARC and barrier methods whilst less effective methods were likely to include withdrawal and other behavioural methods based on a comparison of proportions in the graph and the proportions and categories used in a study of method use among men and women by Firman et al. (2018) also analysing NATSAL-3 data (103). Whilst use of effective contraception was high among the sexually active, there was also use of less effective methods. Figure 2-5 shows how non-use of contraception among the sexually active remained relatively stable across age groups, 16-19 years, 20-24 years and 25-29 years, although it was slightly higher in the lowest age category (16-19 years).

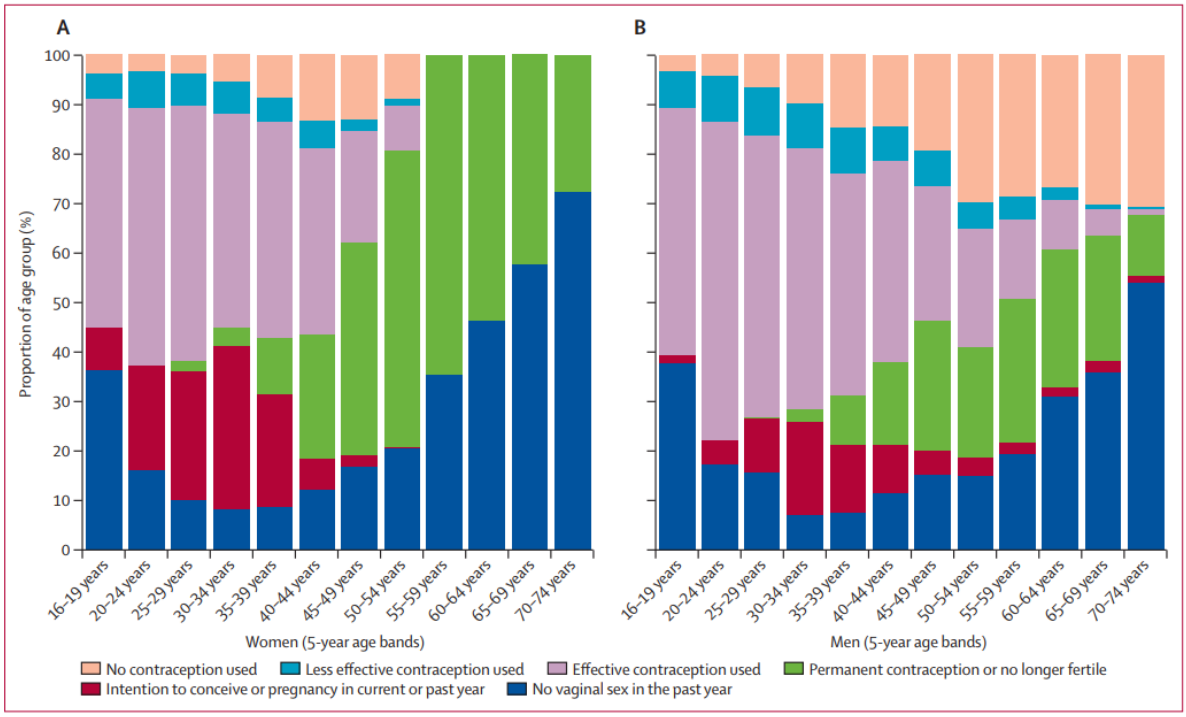


Figure 2-5 Behaviours Relating to Pregnancy Risk in the Year Before Interview, by Age Group (Wellings et al. 2013)

Area disadvantage, socioeconomic position and women’s contraceptive use has been examined using multilevel logistic regression analysis on data from NATSAL-1 (54). Area level socioeconomic disadvantage was determined using the 1991 Population Census of England, Scotland and Wales (152). 9793 women who responded to the survey question on

contraceptive use were included in the analysis out of which 67% reported contraceptive-use in the previous year. They found statistically significant variation between areas in the prevalence of contraceptive use even after adjustment for socioeconomic and sociodemographic characteristics. Other findings included that higher socioeconomic position was strongly associated with use of contraception and that having low levels of formal education or being in a low- or middle-class social group was associated with a decreased likelihood of contraceptive use. Area-level socioeconomic disadvantage was associated with contraceptive use with the women in the most disadvantaged areas less likely to use contraception than those in the least disadvantaged.

Saxena et al. (2006) used NATSAL-1 data to look at factors associated with contraceptive use, this time focusing on ethnicity data (8). Among sexually active women, contraceptive use was significantly lower in all ethnic minority groups when compared to white women, with differences remaining significant after adjusting for educational attainment, deprivation, acculturation (the process of blending between cultures) and parity. Ethnic minority women were also less likely to report use of more effective methods including hormonal contraception and sterilisation. Data was also analysed according to marital status with results showing that among ever-married or cohabiting women, there was lower contraceptive use reported by Indian (78%) and Pakistani women (74%) than by other groups. Among single women, black Caribbean (88%) and black African (82%) women reported using less contraception compared with white (95%) and Indian (100%) women.

Whilst these studies analysing NATSAL-1 data provide valuable evidence that socioeconomic characteristics are determinants of contraceptive use operating at the individual and area level and that contraceptive use is significantly lower in all ethnic minority groups than in white groups, the data is somewhat outdated. This is an important gap in the evidence when considering the marked shifts in unplanned pregnancy in recent decades, particularly in terms of adolescent pregnancies (see section 2.4.3).

2.6.1 Factors Associated with use of Contraceptive Providers

Insight into the services used for contraception again comes from the NATSAL-3 data which was used to identify the services or “sources” used within the past year (70). These sources were: general practice, community contraceptive clinics (including local health authority clinic or sexual health/contraceptive service for young people), retail (including chemist/pharmacy and other types of shop, vending machines or mail order) and non-use of any service.

Restricting the NATSAL-3 sample to 4571 women and 3142 men aged 16 – 44 years who reported having vaginal sex in the past year and those who were not only reliant on sterilisation as their method of contraception, they estimated the prevalence of the use of

sources and examined the associated factors. The most commonly reported source of contraceptive supplies for women was general practice (59.1% [95% CI 57.2 – 61.0]).

Approximately two thirds of women in their 20s used general practice whilst only half of those aged 16-17 years and aged 35-44 years used this source. Factors associated with use of general practice for contraception included living in a rural district, cohabiting with a partner, having minimum or no educational qualifications, and most markedly, identifying as being of white ethnicity.

After retail, the third most commonly used source for contraception among women were community clinics at 23.0% (21.6 – 24.5). At each increasing age category, the proportion of those women using community clinics declined. They were also more commonly used by women in living in urban areas, women living in more deprived areas, women in black and other ethnic minority groups and women not living with their partners. This gives an indication of the groups more likely to be impacted by any changes to community clinic provision.

2.7 Contraceptive Services and Policies in the UK: Overview

In order to get a more in-depth understanding of UK contraceptive provision, it is also necessary to consider the way in which they are funded and governed both now and in the recent past. That contraceptive methods are available without charge in the UK has been credited for the relatively low rates of unplanned pregnancy compared to other high income settings such as the US where contraceptives can be charged to the user (1). The commissioning arrangements for contraceptive services are dependent on the type of method and type of provider, as depicted in Figure 2-6. Contraceptive services also overlap with other, related services such as sexually transmitted infection (STI) testing and treatment and abortion.

2.7.1 Where do Contraceptive Services Sit within UK Healthcare?

The NHS was launched in 1948, based on the principle that good quality healthcare should be universally available, irrespective of wealth (153). It is funded by taxation and is typically free at the point of access, except for certain charges, such as non-contraceptive prescription charges. A devolved system separates responsibility for healthcare to the respecting governing bodies in Northern Ireland, Scotland, England and Wales. NHS England is the largest of these, employing 1.2 million people and catering to a population of 54.3 million.

Although NHS England is connected to government, via The Department of Health (DH) and The Secretary of State for Health, it is an independent body that seeks to improve health and care outcomes for people in England (154). It manages the budget and allocates resources to clinical commissioning groups (CCGs), which are clinically led statutory NHS bodies that plan

and commission local healthcare services (155). They primarily commission secondary care services, including community health services, but are also involved in the commissioning of GP services.

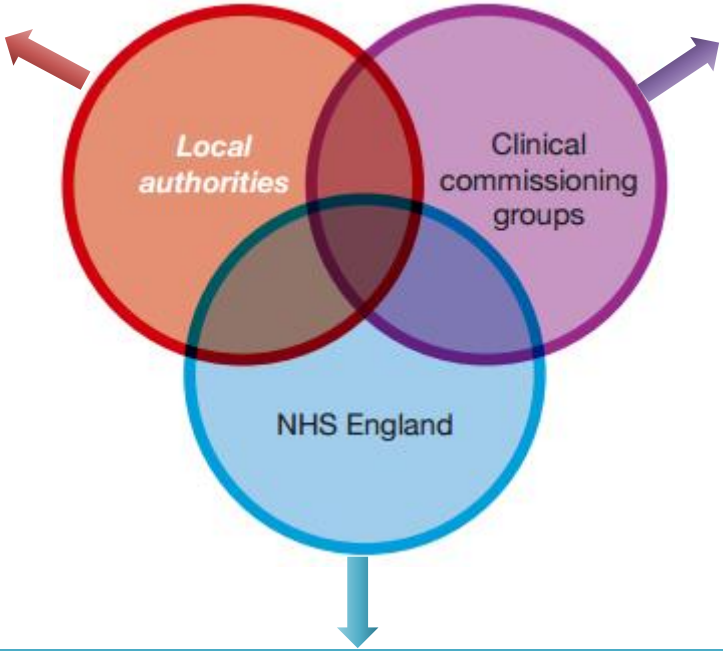
The Health and Social Care Act of 2012 lays out the commissioning responsibilities of local government, CCGs and NHS England (12). Prior to this, contraceptive services were chiefly commissioned by NHS England, but The Health and Social Care Act of 2012 demarcated a greater portion, along with broader sexual health services, to Local Authorities (LAs). This is described as a "whole system" commissioning approach that facilitates service-users' needs for integrated pathways such as having access to a full range of contraceptive methods, including LARC, following access to EC services.

However, the All-Party Parliamentary Group on Sexual and Reproductive Health in the UK (APPG), highlighted structural divisions inherent within this system leading to the potential for issues such as a lack of accountability, a lack of proper oversight of quality and outcomes and "services being commissioned in new silos built around the commissioning structures and not services-users" (156). The Health and Wellbeing Boards set up to increase cohesion between NHS healthcare, social care and public services have also been criticised for failing to prioritise SRH (15). There are also concerns that issues such as long-waiting times in community clinics (11) have been exacerbated due to severe disinvestment in contraceptive services by Local Authorities under financial pressure from the government's austerity measures (13, 14). Difficulties in obtaining appointments are a barrier to contraceptive access from general practice (9), which may intensify in the face of unstable service-delivery and growing financial pressures on NHS England (15).

This is in contrast to the decade preceding the Health and Social Care Act of 2012 when a great deal of government resources were channelled into the provision of contraceptive services and related SRH services, primarily for the purposes of reducing the UK's high rates of adolescent pregnancy.

Local Authorities commission

- **Contraception primarily delivered in community clinics.**
- **The costs of LARC devices.**
- **The prescription or supply of other methods including condoms.**
- **Advice on preventing unplanned pregnancy in specialist services and those commissioned from primary care (GP and community pharmacy) under local public health contracts.**
- **Social care services including wider support for teenage parents.**
- **Young people's sexual health services.**
- **Services in schools.**



Clinical Commissioning Groups commission

- **Abortion services, including STI and HIV testing and contraception provided as part of the abortion pathway (except abortion for fetal anomaly by specialist fetal medicine services).**
- **Female and male sterilisation.**
- **Contraception primarily for gynaecological (non-contraceptive) purposes).**

NHS England commissions

- **Contraceptive services provided as an "additional service" under the GP contract including advice, medical examinations, prescribing of contraceptive substances and appliances (excluding the insertion of intrauterine devices and implants), advice, supplies or prescribing of emergency contraception and advice and/or referral in cases of unplanned pregnancy.**
- **Specialist fetal medicine services, including late surgical termination of pregnancy for fetal anomaly between 13 and 24 gestational weeks.**

Figure 2-6 Commissioning Arrangements for Contraception and Related Reproductive Health Services (Adapted from Public Health England, 2014, updated 2015)

Long-acting reversible contraception, LARC; General practice, GP; Sexually transmitted infections, STI; Human Immunodeficiency Virus, HIV; National Health Service, NHS

2.7.2 National Strategies to Reduce Rates of Unplanned Pregnancy

The UK government launched the Teenage Pregnancy Strategy in 1999 and the National Strategy of Sexual Health and HIV in 2001 (16, 17). These were sustained and multilayered policy interventions including national media campaigns and funding of £26.8 million to increase access to LARCs (19). These have been credited with accelerating the decline in the under 18 conception rate in England and Wales to 18.9 per 1000 in 2016; a 10% decline from the previous year and a 60% decline since 1998 (18-20).

2.7.3 The Teenage Pregnancy Strategy

The British government launched the Teenage Pregnancy Strategy in response to Britain's position as the nation with the highest rate of adolescent conceptions in Western Europe (47.1 per 1000 women aged 15-17 years in England and Wales in 1998) (18, 158). The aim of the programme was to reduce the rate of conceptions in this group by 50% by 2010. Hadley et al. (2016) reviewed the documentation of the strategy and used the World Health Organization's ExpandNet Framework on scaling up strategy to draw conclusions about the features that influenced its perceived success (159).

A key feature was that collaborative action across the government, professional organisations and Non-Governmental Organisations (NGOs) was harnessed by creating appropriate governance structures and legislative changes. The implementation of the strategy was led by the Teenage Pregnancy Unit (TPU), established using cross-government funding. In order to embed the strategy across all areas of government, a minister for teenage pregnancy was appointed in each department which met regularly with the TPU, along with other inter-departmental officials. The work of the TPU was supported by regional and local coordinators as well as local partnership boards and an Independent Advisory Group on Teenage Pregnancy consisting of specialist stakeholders.

Hadley et al. (2016) also emphasised the value of the strategy's tailoring of actions to reflect progress reviews and advances in the evidence-base (159). A mid-course review found that by 2005, the under-18 conception rate had dropped by 11% but with unequal progress across LAs, with some areas increasing by as much as 43%. The strategy was further refined to focus on the parts of the strategy with the greatest empirical support which were the improved sex and relationship education (SRE) strategies and the increase in uptake and effective use of contraception. Areas with slow progress were provided with more resources. The Department of Health channelled £33 million additional funding to increase access to all types of contraception, with particular focus on increasing the publicity and availability of LARC choices for adolescents. Funds were allocated to activities including health professional training on LARC fitting and the launch of a new national campaign called "Sex. Worth Talking About" employing national advertisements to depict conversations between young people and parents and professionals about contraception and related health topics.

Another key feature was that the strategy included the cultivation of a supportive policy environment through incorporating the goals of the Teenage Pregnancy Strategy into broader health programmes and the inclusion of the programme's aim into the performance framework of health, social services and local government.

2.7.4 The National Strategy for Sexual Health and HIV

The National Strategy for Sexual Health and HIV was a 10-year programme launched in 2001 with the aim to improve outcomes of sexual ill-health and modernise sexual health and HIV services in England (17). As indicated by the programme's name, the aims of the strategy were mainly focused on reducing the transmission and prevalence of STIs and Human Immuno-deficiency Virus (HIV). However, one of the five aims of the strategy was to "improve unintended pregnancy rates" with a 2008 review from the Medical Foundation for AIDS and Sexual Health (MedFASH) stating that "a strategic priority is to ensure access to the full range of contraception is available to all, and that this applies to those seeking contraception from general practice as well as from community contraceptive services" (160).

In terms of its contraceptive objective, the programme overlapped with the Teenage Pregnancy Strategy, even including rates of under-18 conceptions in its list of key indicators. However, it also had more expansive indicators which were not age restricted including the proportion of LARC prescriptions in community clinics and general practice and repeat abortions.

2.7.5 Impact of the Strategies

Connolly et al. (2014) analysed data on teenage conception rates and age-specific abortion rates from the Office for National Statistics and the Department of Health and LARC usage data from a number of sources (19). Linear regression methods were used to detect associations with changes in conception and abortion-related outcomes with LARC usage in the period 1998-2011.

During this time, there was a 34.1% decrease in conception rates among women aged under 18 years; a substantial decline, although not quite meeting the original target of 50%. This was found to have a statistically significant association with an increase in LARC usage in this population ($p=0.0024$). Abortion rates among this age group and among women aged 18-19 years also declined during this period. This was found to be significantly associated with increased LARC usage among females under the age of 18 years ($p=0.0029$) and between 18 and 19 years ($p=0.0479$).

The success of the programme was less apparent in other outcomes of interest, particularly for the population aged over 19 years. There was a statistically significant rise in the age-standardised abortion rates among women aged 15 – 44 years as well as an increase in crude

abortion rates in women aged 20 - 24 years and in women aged 25 - 34 years. However, all age groups reported an increase in LARC usage over the study period, with a particularly rapid incline observed from 2007 to 2011, which authors attributed to the additional funding and improvement of the Teenage Pregnancy Strategy implemented after its mid-course review.

Wellings et al. (2016) conducted an observational study using routinely collected data and NATSAL data to examine changes in conception rates from 1994-98 to 2009-13 in relation to spending per-head as a result of the implementation of the Teenage Pregnancy Strategy, socioeconomic deprivation, and region (20). They reported an estimated decrease of 8.2 conceptions (5.8-10.5; $p<0.0001$) after adjustment for socioeconomic deprivation and region. Similarly to Connolly et al. (2014), the authors concluded that the strategy probably contributed to a substantial decline in the number of adolescent conceptions observed. However, they also emphasised that this may have been related to secular trends with global declines in earlier pregnancies likely to be related to people increasing time spent in education and postponing life events such as leaving the family home and settling with partners.

Another area in which the strategies are likely to have been successful was in increasing access of young people to quality SRE. Analysis of data across the three NATSAL surveys found that the proportion of men and women aged 16 - 24 years reporting school lessons as their main source of information about sexual matters increased from 28.2% (95% CI 24.6 to 32.1) in 1990 to 40.3% (95% CI 38.6 to 42.1) in 2012 (161). This is important to note, as receiving sex education from a non-school-based source was positively associated with unplanned pregnancy in analysis of the NATSAL-3 data (1).

The analyses of data from Connolly et al. (2014) and Wellings et al. (2016) provides compelling evidence for the effectiveness of these national strategies, particularly in improving LARC uptake for the reduction in teenage pregnancy rates. However, there is insufficient evidence to determine the active components of these complex interventions and to what extent population trends were influenced by extraneous factors. Wellings et al. (2016) stressed that purely observational strategies are limited in establishing the relative impact of this type of policy intervention and secular trends on relevant outcomes, noting the potential for the observed trend in the conception rate to be subject to regression to the mean over time. The limitations of the learning that can be drawn from the Teenage Pregnancy Strategy are aptly articulated by Hadley et al. (2016), “As teenage pregnancy rates are influenced by a web of inter-connected factors, the strategy was necessarily multi-faceted in its approach. As such, it is not possible to identify direct causative pathways or estimate the relative contributions of each constituent part” (159).

2.7.6 Current National Strategies

Whilst these strategies are no longer operational, the learning and some of the action points are now deeply embedded within sexual and reproductive health policy and provision. The importance of access to a range of methods of contraception, including LARC methods and EC, was highlighted in the Department of Health's "A Framework for Sexual Health Improvement in England" published in 2013, in response to the changes in commissioning to the structure outlined in Figure 2-6 (21). The report also stated that opportunities for improvement were available in the form of technology to support self-care and health education.

Technological innovation is typically not synonymous with large, welfare state organisations like the NHS; it is more commonly associated with industries within the private sector, such as retail and media, with its profit-motivation helping to drive a faster pace of change. However, the current policy environment has seen the boundary between the public and private sector blur, specifically through the proliferation of social enterprises. Social enterprises are businesses set up for the primary purpose of addressing some social or environmental need (22). They are distinctive from private sector businesses which have some social or environmental purpose because any surpluses generated are reinvested to serve their central social or environmental objective. They are considered different to public sector services because of their apparent prioritisation of innovation, cost-efficiency and responsiveness. Social enterprise has grown to fill the gap in public services, including NHS-provided contraceptive services (22).

The current government, as well as those preceding it, have promoted social enterprises in several ways including the £100 million social enterprise investment fund and the publication of reports recommending their advantages to NHS purchasers (23-25). The online service under investigation in this thesis is a type of social enterprise that has been commissioned by the Southwark and Lambeth LAs as part of their sexual health strategy (162). The way technological innovation has been captured by the online contraception service under investigation will be considered in the final sections of this chapter. Firstly, it is necessary to analyse the existing evidence for technological innovation that has been used to improve outcomes related to the effective use of contraception.

2.8 Remote and Digital Contraceptive Counselling Interventions

The online contraception service investigated in this thesis is unique in its complexity and in its availability as an NHS-commissioned service. At the time of writing, no literature has been found that incorporates all elements of the service, in particular the home delivery of free-to-access contraceptive supplies. However, there have been studies concerning remote interaction between contraceptive providers and service-users and the conveyance of contraceptive information using digital or online platforms.

Contraceptive counselling allows women to receive information and advice to enable them to make appropriate choices and can contribute to heightened levels of satisfaction in their attitudes to their contraceptive method, particularly in relation to side effects, which in turn means that they are more likely to use it consistently (80, 121, 163). Improving contraceptive counselling has long been a focus in the literature including interventions that have sought to improve uptake, adherence and acceptability of contraceptive methods with limited success (29, 30). Increasingly, interventions are being designed to take advantage of the ubiquity of internet-enabled devices and near universal mobile phone ownership (31) to deliver contraceptive counselling remotely (32-35).

Given the relative newness in the development of the technological platforms required for remote and digital counselling interventions, the research is limited, so literature searches have expanded beyond the UK context into other high-income countries and, where necessary, low-income settings too. Many studies are from the United States (US) which operates a healthcare system funded mostly through private health insurance rather than the general taxation system operational in the UK. However, the interventions typically target high-risk, uninsured, low income and ethnically diverse populations making them relevant to the intervention context of Lambeth and Southwark.

2.8.1 Interactive Computer-Based Interventions (ICBIs) & Digital Decision Aids

Interactive computer-based interventions (ICBIs) are described by Bailey et al. (2010) as "programmes that provide information and also decision support, behaviour-change support, and/or emotional support for health issues" (164). A related intervention type, more specifically related to executing decisions around contraceptive methods are contraceptive digital decision aids, which are interactive tools developed to convey tailored information and advice to people considering their contraceptive needs (165). The few that have been developed have been designed for patients to use pre-consultation, to facilitate more efficient and successful interactions with health providers (36, 37, 39, 42, 45).

A review of 15 RCTs of ICBIs delivered either on individual computers or online, found these to be effective tools for conveying sexual health information with positive effects reported on outcomes of sexual health knowledge, self-efficacy and sexual behaviour (164). However, this review was largely focused on broad sexual health promotion with outcomes outside the scope of this thesis such as STI testing or general outcomes such as "responsible sexual behaviour". Two of the RCTs included did focus on the prevention of unwanted pregnancy, but the results for this outcome were reported in neither study (166, 167). A study which was excluded from this review due to its longitudinal study design, looked at the effects of an ICBI on both OCPs and barrier methods among female college students in the US aged 18 to 24 years (168). The intervention significantly improved knowledge around subject areas including missed pill instructions and pill benefits. However, with the small sample size (n=58), observational design and the limited generalisability outside of the narrow age group, educational and geographical

context of the study, the findings provide limited understanding of the effectiveness of ICBI to improve OCP knowledge.

My Birth Control is an interactive, tablet-based decision aid developed to promote a shared decision-making approach to the contraceptive counselling process (37). Shared decision-making is where both the medical knowledge of the provider and the patient's knowledge of his or her own values and preferences are recognised and applied to reach collaborative resolutions (169, 170). Formative evaluation using qualitative and quantitative methods suggested that the tool was highly satisfactory and potentially capable of improving contraceptive knowledge outcomes among participants recruited from a waiting room in a safety net clinic in Northern California, USA. A greater proportion of participants using the tool said they were completely satisfied with their choice of method (29%) compared to those receiving standard care (12%), but the difference was not statistically significant (p = 0.06) which may have been due to the small sample size available for analysis (n=83).

A similar decision aid developed in the UK is *My Contraception Tool*, which is freely available online via the Family Planning Association (FPA) website (171) and Brook website (172) to help people make more effective contraceptive choices. According to the only peer-reviewed article published since its launch, it has been used over 50 000 times since 2011, with positive online feedback from users so far (36). Outcomes relating to contraceptive knowledge or use have not been reported.

At a similarly early stage of development is a theory-based counselling mobile-phone application (app) for patients to use whilst in the clinic waiting room pre contraceptive consultation (39). In the pilot study (n = 52) conducted in Chicago in the US, app users had a significantly higher knowledge of contraceptive effectiveness (p = 0.0001) and increased interest in the implant (from 7.1% to 32.1%, p = 0.02) and users were highly satisfied with the app. Another similar, again US-based intervention, labelled as a "touch screen, computer-based contraceptive assessment module" used a small (n=224), three-arm RCT design, allocating participants into a control arm, a group that did the module and received printed, tailored information and a group that did the module but did not get the materials (45). The intervention group that completed the module and received the tailored materials were significantly more likely to continue their contraception compared to the control (OR=5.48; 95% CI 1.72–17.42) whilst no significant differences were found between the intervention group who did the module only but did not get tailored materials when compared to the control group.

Another mobile phone app entitled, *Plan A Birth Control* was first pilot tested among 40 volunteers from an obstetrics and gynaecology clinic in California followed by an RCT among 120 participants who were not using contraception or who were willing to switch method and who were sexually active (42). Participants were randomised to either use the app on a tablet provided to them or to receive contraceptive counselling from a health educator prior to a scheduled visit with their clinician. Whilst the pilot study indicated high levels of satisfaction of

the app, the uptake and knowledge of LARCs did not differ significantly between groups in the RCT (p=0.753 and p=0.30 respectively). This study has limited generalisability as it contained a high proportion of urban college students, however in is notable that in California, there is a program to cater to the contraceptive needs of the under-insured or uninsured, a fact which authors cite as the reason for all participants being able to access their method of choice.

2.8.2 Phone Calls to Enhance Counselling

Whilst the digital decision aid interventions have been developed as pre-consultation tools, the second category of interventions use remote communication to support contraceptive use post-consultation, after a method had been chosen. Two studies were found that used phone calls to supplement face-to-face contraceptive counselling, both conducted in the US, although differing considerably in terms of approach (173, 174).

Berenson & Rahman conducted an RCT to test the effectiveness of either face-to-face behavioural counselling and education (C) or the same intervention followed by monthly phone calls for 6 months (C + P), both compared to the control of standard care (S) (173). The sample of 1155 were attendees of publicly funded reproductive health clinics and comprised mostly women aged between 16 and 24 years who were highly ethnically diverse and occupied lower income groups relative to the rest of the population. Participants randomised to standard care (S) received oral and written instructions and received a 4-month supply of OCPs from a nurse provider. The counselling and education (C) group had an additional 45 minutes of contraceptive counselling using Health Belief Model (HBM) based educational and behavioural techniques. Subjects randomised to the clinic-based plus telephone (C+P) were also contacted weekly until they began their OCPs and then monthly for 6 months by a contraceptive counsellor following their baseline visit. Phone calls included a review of instructions for the correct use of OCPs and missed pill guidance. Neither of the interventions improved OCP adherence compared to the control at 3 (C+P: 58%; C: 50%; S: 55%), 6 (39%; 32%; 37%) or 12 months (20%; 18%; 20%) ($p>0.05$). Nor was there a statistically significant difference in the outcome of pregnancy ($p = 0.06$).

The lack of effectiveness of this study is similar to findings from a study using phone calls to supplement face to face interventions which also found no statistically significant effects of the intervention on contraceptive use and pregnancy rates when tested among adolescents attending a reproductive health clinic in San Francisco (174). The phone call intervention in this study used motivational interviewing (MI), a counselling approach described as “a client-centred, directive method for enhancing intrinsic motivation to change by exploring and resolving ambivalence” (175). This builds on the evidence base that suggests use of MI in face-to-face contraceptive counselling has resulted in positive effects on contraceptive use and uptake (176). Authors cited the most likely reason for the ineffectiveness of the intervention as the inability for counsellors to successfully reach participants, with only 2.7 calls completed per participant rather than the 9 calls stipulated in the protocol. This was suggested to be related to

the nature of participants as members of disadvantaged social groups and authors recommended pursuing text messaging as an alternative platform for delivery.

2.8.3 Text Messaging Interventions

There is a growing body of research using text messaging contraceptive interventions; taking advantage of the increasing popularity of text messaging as a means of communication, particularly among younger age groups (177). Unlike the phone call interventions described above, text-based communication potentially has the capacity to enter into contraceptive users' daily decision-making in an unobtrusive way that removes expectation or pressure to provide an immediate response or engage in a two-way interaction.

A US text messaging intervention was designed to improve appointment attendance among young urban adolescent women using the contraceptive injection, Depo-Provera (40). Participants were allocated to receive the texts over the course of three injection cycles or were subject to standard care which did not involve texts but did include the receipt of an appointment card with the date of the next injection. Most participants were African-American, from low-income households and had internet-enabled smartphones that had unlimited text messaging payment plans. The intervention was effective for the first injection cycle ($p=0.03$) but there was no difference between the intervention and control arm for the subsequent two visits.

A study by Hou et al. (2010) randomised new OCP users recruited from an affiliate Planned Parenthood clinic in Boston to receive daily text-message reminders on OCP adherence (n=41) or not (n=41) (178). The daily text message was, "Please remember to take your birth control pill" sent at the participant's elected time. Participants' OCP use was monitored using an electronic device. At 3 months, there was no statistically significant difference in the mean number of missed pills per cycle between the groups (4.9 ± 3.0 versus 4.6 ± 3.5, $p=0.60$). It is possible that the small sample size (n=41) has meant that there is insufficient power to detect a statistically significant difference. Furthermore, this intervention could be considered low quality due to the repetitive nature of the text messaging. Research indicates a counterproductive effect, including message fatigue, of excessive exposure to similar health-related messages (179).

More promising results came from a study by Castaño et al. (2012) which recruited women aged younger than 25 years accessing OCPs from a SRH clinic in New York run by Planned Parenthood, a non-profit organisation providing services for free or at reduced rates (44). Participants were randomly allocated to receive either standard care (n=482) or the intervention of standard care in addition to a daily text message for 6 months (n=480). Standard care involved OCP dispensation, contraceptive counselling and written educational information. The text messages were designed to cover OCP knowledge across 6 domains: risks; benefits; side effects; use; effectiveness; and mechanisms for action. The primary outcome was self-reported

OCP use at 6 months' follow up and out of the 683 participants providing follow up data, 64% of the intervention group (n=346) were still OCP users versus 54% of the controls (n=337), which was a statistically significant difference (p=0.005). The intervention was also associated with fewer missed pills.

The OCP knowledge outcomes of this trial were reported in a separate study by Hall et al. (2013) (180). They compared mean scores from a 41-item OC knowledge survey at baseline and 6 months between the intervention group. Mean baseline scores were not statistically difference between the intervention and control group (22.8 versus 22.7, p=0.75), but were significantly higher in the intervention than the control group at 6 months (25.5 versus 23.7, p<0.001).

Other mobile phone text messaging interventions of note have been conducted in low income settings. These include the Mobile Technology for Improved Family Planning (MOTIF) intervention to support post-abortion family planning in Cambodia (181) and an intervention delivered via a mobile phone app messaging among young people in Tajikistan (182). The MOTIF trial compared outcomes between an intervention group of 249 women receiving a series of automated, interactive voice messages and counsellor support and a control group of 251 women receiving standard care. Effective contraception use was significantly higher for the intervention group at 4 months (64% versus 46%; relative risk, RR: 1.39; 95% CI: 1.17–1.66) but not at 12 months (50% versus 43%, respectively; RR: 1.16; 95% CI: 0.92–1.47). Although, significantly more women in the intervention group reported using a long-acting contraceptive method at both follow-up times. There was no significant difference between the groups in repeat pregnancies or abortions at 4 or 12 months. McCarthy et al.'s (2018) intervention was developed with young Tajik people; it consisted of tailored, short texts about contraceptive information delivered via an app as well as access to the app containing no behaviour change content, only basic information on contraception and some other non-contraceptive information over a 4 month period (182). The control group had access to the app and texts about trial participation rather than contraception. The control group app was not intended to contain intervention content; however, some contamination took place. Those in the control arm were able to view just under a third of the intervention content via the app due to a misunderstanding between the research collaborators. There was no statistically significant difference between groups for the primary outcome of the proportion of participants reporting effective contraceptive use at 4 months (66% versus 64%, adjusted OR 1.21, 95% CI .80–1.83, p = 0.36). A cluster RCT among female students aged 14 – 24 years in schools in Accra, Ghana to either text messages with reproductive health information (n = 12), text messages with reproductive quizzes (n = 12) and control (n = 14) (41). Both intervention arms had an increase in knowledge at 3 and 15 months; the quiz intervention more so than the arm with unidirectional texts. Interestingly, this study also reported that both intervention arms had fewer self-reported pregnancies than the control after adjusting for sociodemographic variables and knowledge at baseline for the unidirectional text intervention (OR = 0.14; 95% CI = 0.03, 0.71) and quiz intervention (OR = 0.15; 95% CI = 0.03, 0.86) respectively. The quiz intervention was positively

associated with having sex without a condom among those in the sample who were sexually active which authors attributed to a focus on pregnancy-prevention over STI risk. Another text messaging study in Kenya found that texts containing contraceptive information improved knowledge compared to a control group ($p < 0.001$) but that it did not increase use of contraception ($p = 0.94$) (43).

The Castaño et al. (2012) study, Hou et al. (2010) study and the MOTIF trial were included in Smith et al.'s (2015) review of mobile phone-based interventions stated broadly promising effects on contraceptive use and adherence from five RCTs, although authors remained cautious as the evidence was limited and the longer-term effects, particularly on the outcome of unplanned pregnancy, were not yet known (32). Since this review there have been some studies indicating text messaging interventions could be preventative of pregnancy among young people although these have relied only on self-reported data and were conducted in a very different setting to the context under investigation in this thesis (34, 43).

2.8.4 Overall Findings of Literature Review on Remote and Digital Counselling Interventions

The literature review has covered some of the key areas of remote and digital interventions, varying in the quality of evidence and the intervention approaches. General outcomes pertaining to sexual health knowledge and behaviour may be improved with ICBI, but evidence on their specific effect on unplanned pregnancy and contraceptive knowledge, access and use is limited (164). There is a lack of quality evidence around the effectiveness of digital decision aids, but the studies indicate a generally high level of satisfaction among pilot testers (36, 37, 39). One of the studies using a more robust RCT design found that a computer-based assessment intervention was only effective in improving contraceptive continuation when reinforced with tailored handouts (45). Another RCT found that an app delivered on a tablet did not improve uptake or knowledge of LARC (42). The few studies testing interventions incorporating phone calls do not indicate that this approach is particularly effective, particularly when targeting young people for whom text messaging is a preferred mode of communication (173, 183). There have been mixed results across the various text messaging interventions but some promising findings on OCP continuation (184) and OCP knowledge (180) and even pregnancy prevention (43). However, further research using long-term outcomes and objective data would be of interest.

Authors of the Castaño et al. (2012) study state the value of their intervention to improve contraceptive outcomes in a way that "adapts the health system" without requiring extensive resources or alterations to existing counselling procedures. This is an important observation when considering that the online contraception service investigated in this thesis has been commissioned to complement the existing landscape of services rather than to act as a standalone intervention. Authors also stress the importance of the study population being young and containing substantial proportions of ethnic minority participants; groups which are at high-risk of unplanned pregnancy both in the US and UK. This is also highly relevant to the

intervention context of Lambeth and Southwark, which contains an ethnically diverse population with relatively high levels of deprivation and unplanned pregnancy rates that exceed national averages.

2.9 The Intervention Context: Lambeth and Southwark

Lambeth and Southwark are adjacent south London boroughs. They are some of the largest and most residential of any inner London boroughs with twice the population density of London as a whole (185). The population structures of both boroughs are skewed toward younger, economically-active age groups with higher proportions of those aged 20 – 39 years when compared to London as a whole (42% in Southwark; 44% Lambeth compared to 35% in London).

The intervention that is under investigation in this thesis is SH:24's online contraception service. This, along with SH:24's broader sexual and reproductive health services have been commissioned by Lambeth and Southwark as part of their strategy to reduce the relatively high rates of poor sexual and reproductive health outcomes. Prior to exploring the online service and its position in the local health strategy, this section will present some further detail regarding the target population.

2.9.1 Ethnic Diversity

Both boroughs are ethnically diverse. In Lambeth 59% of the population describes themselves as being of white ethnic group and 24% of Lambeth residents identify as black African, black Caribbean or black British (Figure 2-7). This diversity is variable across age bands, with 80% of 10 – 19 year olds describing themselves as non-white British, compared to 50% of 20 – 29 year olds (47). Figure 2-7 shows that Southwark has 55% of the population identifying as white and 45% of the population belonging to black, Asian and minority ethnic (BAME) groups. Those identifying as one of the categories in the black ethnic group constitute the largest quantity of BAME residents at 24%. Both Lambeth and Southwark have larger proportions of residents describing themselves as being of black ethnic group than in London, where the proportion is 17% (46). They do, however, have relatively small proportions of residents identifying as Asian (7% Asian ethnicity in Lambeth and 10% in Southwark) compared to London which is 21%.

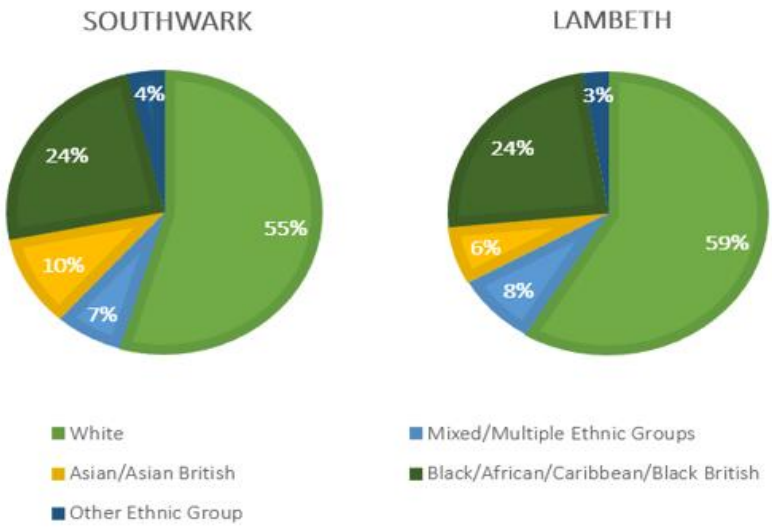


Figure 2-7 Ethnicity data, Southwark and Lambeth, 2016 Categories are comprised of multiple collapsed categories (Data from Greater London Authority, 2017).

2.9.2 Deprivation

In England, the official measure of deprivation is the Index of Multiple Deprivation (IMD) (186). This operates as a ranking system where every small area in England is scored and then ranked from 1 (most deprived area) to 32 844 (least deprived area). These small areas are called Lower-layer Super Output Areas (LSOAs), typically including around 1 500 people or around 650 households, and are based on data from the 2011 Census (187). It is common to divide these 32 844 LSOAs into 10 equal groups, or deciles, or further still, into quintiles. The measure is based on information from seven domain indices which are: 1) Income (including income deprivation affecting children and income deprivation affecting older people); 2) Employment; 3) Health deprivation and disability; 4) Education, Skills and Training Deprivation (including sub-domains for children and young people and adults); 5) Barriers to housing and services; 6) Crime; and 7) Living environment (including sub-domains for outdoor and indoor living environments). Every LSOA is given a score for each of the domains and a total score for the index which is then used to rank all the LSOAs in England thus enabling identification of how deprived a given area is in relation to others.

Southwark is ranked 40th most deprived out of the 326 national LAs, and is the ninth most deprived among the 33 LAs in London (188). The variation in deprivation across the area can be seen in the map in Figure 2-8. Approximately 38% of Southwark residents live in LSOAs which are among the most deprived in England. Lambeth is ranked 44th most deprived out of the 326 national LAs and is the eight most deprived in London (47). As shown in Figure 2-8, Lambeth also contains both deprived and relatively affluent LSOAs in close proximity to one another. Around 31% of residents live in LSOAs ranked in the 20% most deprived areas nationally (47).

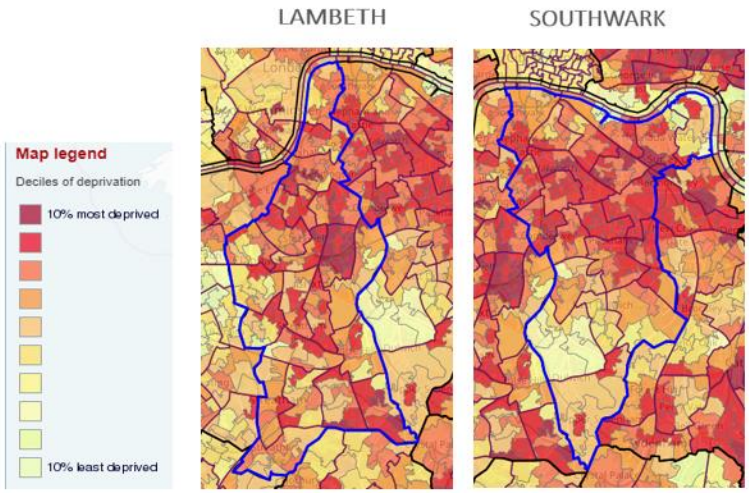


Figure 2-8 Lambeth and Southwark Map of Index of Multiple Deprivation Deciles, 2015 (Ministry of Housing, Communities and Local Government, 2015)

2.9.3 Local Measures of Unplanned Pregnancy

In line with the national picture, the conception rate in these localised areas has declined. In 2016, the conception rate in Lambeth was 47.4 births per 1000 women aged 15 – 44 years and 54.3 per 1000 in Southwark (189). Available indicators of localised rates of unplanned pregnancy are abortion rates and under 18 conception rates.

The age standardised abortion rate per 1000 resident women aged 15 – 44 years in Lambeth and Southwark was 20.7 and 20.8 respectively, which are similar to the overall London rate but higher than the national rate (48). The total number of reported abortions for residents in Lambeth in 2016 was 1895, 43% of which were repeat abortions; 32% were repeat abortions in women aged under 25 and 48% were repeat abortions for women aged 25 and above. In Southwark in 2016, 30% of conceptions resulted in abortion (18). The total number of reported abortions for residents in Southwark in 2016 was 1833, 44% of which were repeat abortions; 30% were repeat abortions in women aged under 25 and 51% were repeat abortions for women aged 25 and above (190). In both boroughs, repeat abortions are more common among black African and black Caribbean women than in other ethnic groups (189). In 2017, 11% of Lambeth women aged under 19 years, and 13.1% of Southwark women aged under 19 had more than one abortion in that year alone. It has been posited that this is related to declines in the rates of LARC uptake following abortions (191).

The conception rate per 1000 women under 18 years of age was 22.8 in Lambeth and 25.9 in Southwark (18). Figure 2-9 depicts the drastic declines in teenage conceptions since 1998 as the boroughs are likely to have benefitted from the Teenage Pregnancy Strategy and improved access to LARC. However, Lambeth and Southwark are clear examples of the inequalities that are apparent within the national picture (section 2.4.3). These localised rates exceed both the national rate and the London rate of 17.1 per 1000 women under 18 years (18).

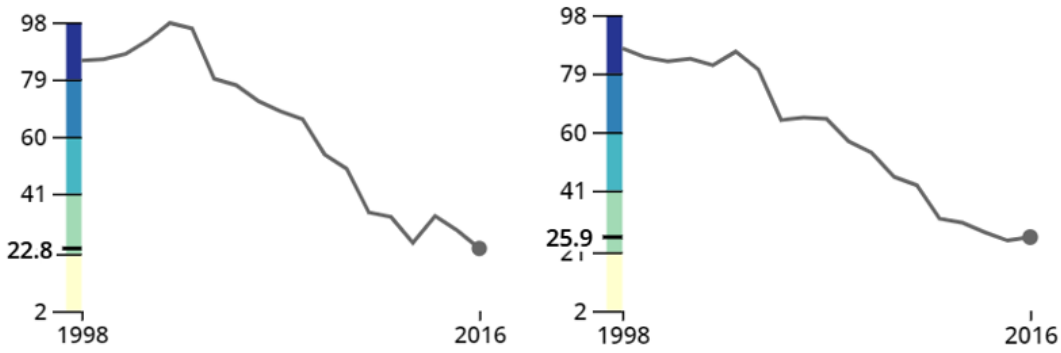


Figure 2-9 Under-18 Conception Rates by Local Authority; Lambeth (left) 22.8 per 1000 women aged 15 to 17, Southwark (right) 25.9 per 1000 women aged 15 - 17 in 2016 (Office for National Statistics, 2018).

Whilst not an indicator of unplanned pregnancy, it is pertinent that rates of EC use and repeat EC use are higher in the intervention context than both England and London. According to the latest data published in the new 2018 – 23 sexual health strategy for Lambeth, Southwark and Lewisham, 90% of women in these boroughs self-reported previous EC use (189). Around 60% of Southwark EC users reported previous use within the previous 6 months. Whilst encouraging that there may be good access to EC for women in these boroughs, authors of the strategy stress that this is a clear indicator of unmet need for more effective methods of contraception, such as LARC methods, which have lower rates of uptake in these areas compared to the rest of the country.

2.9.4 Local Strategies to Reduce Rates of Unplanned Pregnancy

Lambeth and Southwark councils published a joint sexual health strategy (also with Lewisham council), outlining their vision to improve sexual health in the boroughs for the period 2014-17 in a context of disproportionately poor sexual and reproductive health outcomes and over-stretched, under-funded services (162). The strategy incorporated the then embryonic online contraception service (one component of a broader online sexual and reproductive health service), called SH:24, stating the boroughs' support for "innovation and making best use of new technologies to improve our sexual health services and ensure best value".

The strategy was published in the aftermath of the Health and Social Care Act 2012 and so the challenges of the financial context were prominent throughout. Authors stated that with cost pressures and clinical activity continuing to rise it was important to focus on cost effective and preventative measures. As stated in section 2.5.3, LARC methods are highly cost effective and as such, the increase in access to these was emphasised in the report. SH:24 was also cited as a cost-effective strategy to expand clinical services at a lower cost per contact.

Now available in draft form is the boroughs' sexual health strategy for 2018-23 (189). The report acknowledges some key achievements since the last strategy, such as the continued reduction in teenage pregnancies and a slight increase in the proportion choosing LARC methods in community clinics. However, the main emphasis is on the ongoing challenges, in particular, the

financial challenges which continue to impact service delivery resulting in the closure of some community clinics. They cite “wider system pressures” on general practice and community clinics leading to difficulties in people getting contraceptive appointments and being unable to obtain walk-in slots.

The strategy for 2018-23 centres around four key priorities for sexual and reproductive health, one of which is “good reproductive health across the life course” (189). They elaborate that this is the ambition that all residents “have the skills, knowledge, and access to services that allow them to effectively manage their fertility and reproductive health”. The publication also contains findings from focus groups with women across Lambeth, Southwark and Lewisham in 2018 concerning their views on contraception. These encompass the myriad barriers that prevent effective access to contraception and inhibit women making confident and informed contraceptive choices. These include difficulties in accessing services, absent or incorrect knowledge and low confidence around contraception, negative opinions of interactions with health care professionals and the social stigma associated with access. However, it should be noted that in this draft report, there are no further details of the methods employed for the study or the sampling procedure used.

Another finding from this focus group is that women stated a preference for expanded choice in access, enabling them to attend face-to-face appointments with ease, access services from their local pharmacies, as well as online and phone access from home. This, as well as the proven record of popularity of the SH:24 service in Lambeth and Southwark in its period of availability since the previous strategy, bolsters SH:24’s position in the new strategy as a potentially cost-effective solution to alleviate the burden of demand of sexual and reproductive health services on under-resourced community clinics and general practice.

2.10 The Intervention: SH:24’s Online Contraception Service

The complex intervention under investigation in this thesis is called SH:24, and is a type of social enterprise, called a community interest company (CIC), that has been commissioned to provide sexual and reproductive health services in Lambeth and Southwark. SH:24, like other social enterprises, can be considered as a type of ‘hybrid’ organisation (26), with primarily social objectives in the form of improving sexual and reproductive health outcomes for the local population, but arguably, with the capacity for efficiency and innovation typically seen in the private sector (27, 28).

This PhD commenced in October 2014, shortly after the publication of the boroughs’ 2014-18 sexual health strategy. In this strategy SH:24 is described as a service that will “expand access to clinical services: contraception and diagnosis and management of sexually transmitted infection via a web based service (24 hours a day) linked to telephone and specialist clinic support”. Whilst giving an overarching aim of the intervention and how it might operate, the specifics of the service, particularly with regard to the contraceptive element, were largely

unknown. SH:24 uses a responsive and iterative design process. Reflecting this, the intended elements of the contraceptive service were uncertain throughout the initial planning phase. Until early 2016 the service was intended to launch with EC provision involving access to LNG or UPA, most likely via home delivery. To reflect this, the original plans for this thesis (as submitted as part of my final upgrade thesis for transfer from MPhil to PhD and oral examination which took place in September 2015) involved evaluation of this intended online EC service. The protocols for these studies can be seen in Appendices A[1] and B. Due to shifts in commissioning priorities in the boroughs, this service input was postponed, and the development of a service providing access to contraceptive information and supplies of OCPs became the new focus. At the time of writing, the online contraception service can be summarised as online information and clinical assessment with combined and progestogen only oral contraceptive pills ordered online and sent home, free of charge and all supported via text or phone calls between the service-user and provider. Screenshots of the ordering process are provided in Appendix C. What follows are details of the intervention based on a review of the service made on 8th December 2017.

Service-users visiting the SH:24 website can order OCPs to be delivered to their homes provided they are residents of Lambeth and Southwark, they are aged 18 years or over and upon successful completion of the online consultation process, which primarily involves checking that service-users meet UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) (192) for their chosen method.

There are two options for OCPs, either Desogestrel (75 micrograms) - a brand of POP or Levonorgestrel/ Ethinylestradiol (150 micrograms) – a brand of COC. The ordering process for COC entails some additional questions compared to the POP process due to the associated medical contraindications. This includes a request for blood pressure (BP) and body mass index (BMI) measurements. Service-users who are unaware of these measurements are provided with a list of local services - namely pharmacies - that have self-service BP and/or BMI machines. Service-users who require information or advice regarding the consultation process or the contraceptive method they receive are able to communicate via text message and telephone call to a contraceptive nurse or doctor. The online consultation process reveals some circumstances requiring a more in-depth interaction with a clinician, for example if a service-user indicates that they have had recent unprotected sexual intercourse or if they report an unusual BP measurement. Whether or not the service-user goes on to order COC or POP, or is advised to visit a face-to-face service, will be dependent on the clinical judgement of the

[1] "The Feasibility and Acceptability of an Internet-based EC service" received approval from London – Camberwell St Giles Research Ethics Committee (reference 15/LO/2015), 22nd December 2015 but had to be postponed due to the changes to the intervention development plans.

healthcare professional that they speak to. The standard quantity of OCPs provided is 3 months, but clinicians may deem it appropriate to provide a 6 months' supply if the service-user has ordered OCPs previously or if their communication indicates they have been regular users via access to other services.

In the event that the online consultation process is straight-forward and not requiring any further communication with a clinician, the service-user will reach a confirmation page and the data for the order will be logged. If there are no medical issues to be addressed and provided the service-user does not communicate a request to cancel their order, the pills will be dispatched to their home address.

Prior to the expiration of their first OCP supply, SH:24 sends a text to remind the service-users to order a repeat supply, either via replying to the text - to initiate a text-based conversation to get the necessary information for a second supply to be sent - or by prompting the service- user to re-order from the website.

The evaluation of the SH:24 sexual and reproductive health services has been ongoing since 2013 and several studies have been published, mostly focused on the effectiveness of the STI testing and treatment element of the intervention (193-197). However, contraceptive users represent a different population and the nature of contraception as a health behaviour is distinct from sexual health and broader health concerns (which will be explored further in the following chapter), thus the conclusions that can be drawn around the effects of an online contraceptive service of this nature and complexity remain largely without a robust evidence base. This thesis seeks to lay the foundations for this evidence base; presenting the first research on the impact of a complex, online contraceptive intervention on the population of Lambeth and Southwark.

2.11 Summary of Chapter 2

- Although the overall conception rate in England and Wales is at its lowest since 2005, it estimated that one in six pregnancies are unplanned and that there are national and local inequalities in the distribution of poor reproductive health outcomes including teenage pregnancy, repeat abortions and access to contraception.
- Women in the UK have free access to a range of contraceptive methods from various providers including community clinics and general practice. Since the Health & Social Care Act in 2012, much of contraceptive provision, including the highly effective LARC methods, are commissioned by LAs and have been subject to severe disinvestment in services.
- National and local strategies to increase access to contraception in a context of scarce resources and growing demand have included the promotion of social enterprises and use of technological innovation.

- The literature available for remote and digital contraceptive interventions suggest that digital decision aids have potential and that text messaging could be effective in counselling women for improved contraceptive outcomes in the short-term.
- Lambeth and Southwark are densely populated, ethnically diverse London boroughs with high levels of deprivation and high rates of unplanned pregnancy relative to the rest of the capital and the country.
- The boroughs require cost-effective strategies to reduce these rates so have commissioned SH:24, online contraception, a social enterprise which capitalises on the ubiquity of internet-enabled devices and apparent preferences for remote communication in the population. This is the intervention under investigation in this thesis and is the first to provide not only remote and digital interaction and information, but also free-to-access supplies of contraception delivered to the home.

3 Theoretical Framework: Contraception as Practice

3.1 Chapter Overview

The previous chapter set the scene for the online contraception service through consideration of national data on unplanned pregnancy and literature on strategies to improve access to and effective use of a range of contraceptive methods. This chapter uses elements of Bourdieu's Theory of Practice to generate an overarching theoretical framework for this thesis. This provides the lens through which to consider contraceptive decision-making and activities as a unique practice and then, to reflect on online contraception as a fundamental shift in provision that may have profound implications for this practice. The framework facilities the sociological interpretation of the empirical findings in this thesis, thus strengthening understanding of online interventions within this research context and beyond.

3.2 Rationale

Identifying, accessing and using a contraceptive method involves activities and decisions which are unique among other areas of health due to the emphasis on method choice and the nature of pregnancy as the potential outcome of ineffective use or non-use. Bourdieu's Theory of Practice is conducive for specific application to contraception because it provides a framework for understanding the interplay of agency and structure in contraceptive decision-making, the power dynamics involved in patient-provider interactions and the inequalities related to contraceptive use and access. Furthermore, the service under investigation in this thesis is novel with no precedence in the literature of direct relevance to this platform of contraception delivery and its position within the UK health system. Therefore, a sociological lens allows a more abstract consideration of the extent to which this alters existing models of contraceptive provision using the literature on remote and digital interventions introduced in Chapter 2.

This is a marked shift away from the theoretical approaches extant in the contraceptive literature. Health behaviour models are commonly used, typically with a basis in a social cognition approach, focusing on the individual thought processes intervening between observable stimuli and responses (198-201), such as the Health Belief Model (HBM) (173, 202, 203). Those who have applied Bourdieu's concepts to health more generally have argued that although these theories do consider individual behaviour within a broader social and political context, the central focus on the individual psychology of decisions limits understanding of the underlying factors that generate collective patterns of health behaviours (204). This understanding is facilitated through Bourdieu's inimitable concepts of capital, habitus and field which will be defined and applied to contraceptive practice in this chapter.

This overarching framework is integrated with a narrower, theory of change conceptual framework, which has a stricter focus on the internal processes of the intervention and its localised impact on the target population (Chapter 4). Generating and developing theory using

both a sociological approach and a conceptual framework facilitates not only a context-specific appreciation of findings but also a more abstract interpretation and contextualisation within wider society; establishing the knowledge base for this novel intervention in order for it to expand and develop for broader theorising in this new era of digitisation and remote and online health. This chapter aims to outline the theoretical framework, using selected concepts from Bourdieu's body of work as the lens through which to consider contraceptive decision-making and activities as a unique practice and then, to reflect on online contraception as a fundamental shift in provision that may have profound implications for this practice.

3.3 Defining terminology

To understand and apply Bourdieu's work to conceptualise contraception as practice, it is first necessary to define the terminology and confine the sociological literature to its application within this and subsequent chapters.

3.3.1 Agency and Structure

In the mid-20th century, German sociologist, Max Weber introduced the term "Lebensführung", translated into English as "life choices", to sum up the process of agency that enables one to conduct and manage life by critically evaluating and choosing particular courses of action (205, 206). For Weber, life choices are anchored within structural conditions, such as income, property and the normative rules of the community (207). Weber used the term "Lebenschancen", translated to "life chances", to describe the structural forces that operate differentially across society, enabling and constraining choice-based life-conduct, and reinforcing the advantages and disadvantages of comparative class circumstances (208). Another of the founders of modern sociology, Émilie Durkheim, similarly grounded agency within structure, asserting that neither individual or collective autonomy could be possible without social structure to constrain and enable its course (209, 210).

Conceptualisations of agency and structure have since become even more inextricably intertwined, whereby structure not only shapes agency but is a *product* of agency. Anthony Giddens formulated the notion of "the duality of structure", meaning that structures are "both the medium and the outcome of the practices which constitute social systems" (211). Giddens considered these social practices to be dictated by actors' resources and knowledge of the abstract rules of social conduct. Sewell built upon the work of Giddens, referring to these abstract rules as "cultural schemas", which, combined with tangible and material resources, comprise structure (212). Sewell emphasises that if human agency reproduces structure, then it follows that structure is dynamic; able to transform through individual or collective action.

Implicit in the notion of agency is that people make (conscious or unconscious) choices among an array of alternative forms of behaviour (209, 212). This operates on a continuum; at one end agency leads to structural reproduction and on the other, structural transformation (209). Even

structural reproduction requires a considered process of decision-making that is inherently temporal, involving recollection of the past, the projection of future actions and critical evaluation of the present situation (213). Structural transformation at its most extreme is the result of revolution, but even the day-to-day, individual agency required to apply cultural schemas and resources to unfamiliar or unforeseen situations, contributes some subtle transformation to structure. There are a number of factors that influence the positioning of agency along this continuum including the durability of the structure in question and the differential levels of power and access experienced by individual agents. These structural inequalities have important implications when considering agency in the domain of health.

3.3.2 Bourdieu's Practice Theory

Weber's concepts of life choices and life chances, whilst laying the foundations for the understanding of the interplay between agency and structure, have been deemed insufficient when considering health-based conduct, as they leave little room for consideration of the day-to-day choices that determine more contemporary notions of "health lifestyles" (214, 215). For this, it is necessary to turn to the theorising of Pierre Bourdieu, one of the foremost sociologists of the late 20th century, whose work has facilitated an appreciation of the recursive and co-dependent influences of structure and agency on day-to-day, health related practices (214, 216-227). Schatzki (1997) defines practices as "interwoven activities within a given social domain" (228). However, deeper appreciation of Bourdieu's notion of practice requires consideration of the components of the theory and its ontological basis.

Central to Bourdieu's practice theory is in the transcendence of the agency/structure divide and his arguments against the dichotomous concepts of objectivism and subjectivism within activities which are daily and routinised (229, 230). For Bourdieu, objectivism neglects the active negotiation and strategic action that constitute everyday decision-making. Meanwhile, subjectivism fails to appreciate the external and economic context of decision-making, focusing on the reason and rationality of the consciousness. Bourdieu's concept of habitus is considered the cornerstone of his social architecture and, along with its interconnectedness with capital and field or field(s), represents a paradigm shift away from the objectivism/subjectivism and agency/structure dichotomies (216, 217).

Habitus is an acquired system of dispositions that reflect past experiences, traditions and habits that generate and organise how people act and think in accordance with the social context; this sets structural limits for action whilst also contributing to structuring properties themselves (230, 231). Habitus makes individual practice inherently social through the process of unifying and reinforcing experience to engender homogeneity in social groups (232). This homogeneity is also what leads to practices being conventional and taken for granted (233).

The consequence of the power of habitus to set structural limits for action is that practices can endure within groups, across time. In "Outline of a Theory of Practice", Bourdieu describes

“conditions of existence which, in imposing different definitions of the impossible, the possible, and the probable, cause one group to experience as natural or reasonable practices or aspirations which another group finds unthinkable or scandalous and vice versa” (234). The most common critique of Bourdieu’s notion of habitus is that in centralising social structures as setting the parameters for behaviour, both by dictating normative patterns and by embedding action as intuitive through class-based patterns of experience, the value of agency is underplayed and practice becomes deterministic (214, 215). Others advocate that Bourdieu’s habitus does encapsulate possibilities of agency-driven transformation or revolution as it is constantly affected by the varied experiences that people encounter (216, 227, 235). This thesis follows the interpretation of Cockerham (2005) which states that, whilst habitus can initiate alterations in the dispositions of which it is comprised, the hierarchies of class and predictability of experiences within social classes will see to it that “usual and practical modes of behaving – not unpredictable novelty – typically prevail” (227).

To understand Bourdieu’s perception of social class requires a more in-depth consideration of capital, which he described as a class phenomenon (218). Capital refers to the cultural or social resources that actors exercise consciously or subconsciously within social interactions that function as a “social relation of power” (218, 236). The distribution of capital is a representation of the structure of the social world at a given moment in time that dictates social functioning in a durable way by influencing the potential for success or failure of practices (236). Capital has three main guises, variable in their institutionalised forms, but not so distinct as to prevent the conversion of one guise to another:

1) Economic capital - which is immediately and directly convertible to money and can be institutionalised into property rights.
2) Cultural capital – which is conditionally convertible into economic capital and can be institutionalised in the form of educational qualifications.
3) Social capital – constituted by social connections that are conditionally convertible into economic capital and can be institutionalised in the form of membership or a position within a powerful or prestigious institution or, at the more extreme end, a title of nobility.

These different forms of capital are the resources that are at stake within the fields that practices are situated (216). Field is the social space and a network of relations within which there is a specific distribution of power, which Bourdieu called a “field of forces” but also a “field of struggle” as actors seek to maintain or contest this power distribution (218, 237). The objectivist ontology of a positivist paradigm separates reality from human perception so that it is knowable through careful observation and inductive reasoning, typically using quantitative methods. The objectivist epistemology with terms such as “context” or “social background” is therefore deemed insufficient to capture the conflictual character of social life with its latent patterns of interest and struggle (230, 238). The concept of field also diverges from the positivist notion of distinct boundaries between fields, since boundaries are themselves objects of contestation. Field is therefore a way to narrow the scope of an investigation and capture the variety of factors that influence behaviour.

It has been established that Bourdieu's theory of practice is inherently relational. There is a specific relationship between field and capital which is linked to social class. People's accumulation and dispensation of their specific forms of capital will group people together within a social space and determine their power position within the field in question (226). There will be certain individuals and groups better equipped for their practices within the field thus practices become the product and the driver of social class and the associated, homogenised capital of that group (239).

Habitus is also relationally bound with capital and field, which is summarised in Bourdieu's formula:

[(habitus) (capital)] + field = practice (240).

Practice is therefore the result of the dynamic interrelationship between habitus, capital and field established at a point in time. Collyer et al. (2015) interprets this as: "*…in their daily lives, individuals act unconsciously according to their habitus and sometimes make choices and develop strategies as they engage with various social fields, gathering and deploying forms of capital" (218).*

3.4 Application of Bourdieu's Practice Theory to Contraception

Whilst Bourdieu's Practice Theory has not been explicitly applied to the specific domain of contraception, it has been useful in considering health inequalities (214, 220), the capacity for agency in health behaviour (216) and the extent to which knowledge can affect health behaviour (217), health lifestyles (227) and healthcare choice (218). It is conducive for the more specific application to contraception because it provides a framework for understanding the interplay of agency and structure in contraceptive decision-making, the power dynamics involved in patient-provider relationships and the health inequalities apparent in contraceptive outcomes across populations.

Hall (2012) defined contraceptive behaviour as "activities involved in the process of identifying and using a contraceptive method to prevent pregnancy and can include specific actions such as contraceptive initiation (to begin using a contraceptive method), continuation or discontinuation (to maintain or stop use of a contraceptive method), misuse (interrupted, omitted or mistimed use of contraceptive method), nonuse, and more broadly, compliance and adherence (general terms often used to denote any or all of the former contraceptive behaviour terms)" (202). Although a definition of contraceptive behaviour rather than practice, it remains apt from a Bourdieusian sociological perspective because it comprises the routinised, daily decision-making that constitute interwoven contraceptive activities. It follows then, that contraceptive practice is generated by habitus; engendering homogeneity in contraceptive outcomes within social groups. Access to supplies and information necessitates interaction with health professionals within the field of contraceptive healthcare - an interaction which requires

contraceptive-users to deploy and possibly acquire forms of capital, such as the knowledge and skills to choose a contraceptive method that is appropriate and effective.

3.4.1 The Interplay of Agency and Structure on Contraceptive Practice

Bourdieu's transcendence of the agency/structure divide facilitates understanding of contraceptive practice because this form of healthcare practice is unique in its emphasis on patient choice. This is reflected in national guidelines which centralise choice as one of the fundamental indicators of quality in contraceptive provision (6). The guidelines state that women should have their choice of method, their choice of provider and that their decision-making should be enabled through access to accurate and up-to-date information. Thus, whilst the agency of the patient is repeatedly highlighted, structural factors are nonetheless significant, not least in terms of access to healthcare services for information and supplies.

Agency may be of heightened importance in this area of health practice as contraceptive decisions are typically not instigated by illness and therefore lack many of the vulnerabilities associated with poor health (241). Rather, the emphasis is on risk awareness and prevention, requiring the agency advocated by Hochbaum in his analysis of the patient role required to engage in health screening (242). In addition, the goal to avoid potentially negative outcomes associated with ill health is instead replaced with the goal to prevent pregnancy, an outcome that can elicit a range of patient responses including ambivalence (1, 243). Therefore, decision-making around contraception is beset with complexities influenced by individual attitudes and temporal circumstances and values (243-246). This personalised context contributes to women reportedly having a more pronounced preference to exercise autonomy in their contraceptive choices compared to other health concerns (247-249). There are, however, distinct parameters to this autonomy as contraceptive providers are still the gatekeepers of medical information and supplies of non-barrier methods of contraception.

The notion of agency in health conveyed by Abel & Frohlich (2012) is that it is constituted by "the active acquisition and development" of health-relevant capital (214). They emphasise the social element in the transmission of this capital between individuals, families and peer groups. Regarding the exercise of choice in contraceptive decisions, capital in the form of knowledge of methods, where and how to access these methods, their associated side-effects and effective use, all need to be acquired and developed.

3.4.2 Power Dynamics in Patient-Provider Interactions

Through a Bourdieusian lens, patient-provider interactions including counselling, can be considered the embodiment of the field of contraception. This interaction can allow women to receive information and advice to enable them to make appropriate choices and can contribute to heightened levels of satisfaction in their attitudes to their contraceptive method, particularly in relation to side effects, which in turn can mean that they are more likely to use it consistently

(80, 121, 163). In the case of OCPs, perceptions or experiences of side effects are often cited as key contributors to women's decisions about discontinuation and inconsistent use (79-81) so should be mediated by the quality of counselling by providers (250) with Rosenberg and colleagues concluding that: "counselling should emphasise the possibility of side effects, stressing the fact that most will be transient" (75). Guidelines contain the advice that "women should be informed thoroughly about all potential side effects when starting contraception" in addition to information about non-contraceptive health benefits and risks associated with use (83).

The power dynamic within this field is inevitably skewed towards the provider who is intimately familiar with the field dynamics and social patterns and has the dominant form of cultural capital with regard to both professional status and the relevant medical knowledge and expertise (216, 231). Conversely, the patient, or contraceptive service-user, is in a foreign field in which her habitus is less attuned, and her relevant cultural capital is likely to be at a deficit. This is likely to constrain her capacity for agency and lead to her reliance on the provider to guide her decision-making (216, 235). This is noteworthy when considering the literature that suggests women having heightened preferences to exercise their agency in their contraceptive choices, mentioned in section 3.4.1. However, the flow of capital is not purely one-sided, as the patient must provide information about herself, such as her medical history and her relationship status, in order for the provider to dispense appropriate advice. Contraceptive counselling is the process through which this information, or capital is exchanged, with emphasis on the approach employed by the provider to execute the interaction for the best possible outcome for the patient.

The nature of this outcome may be an area of power contestation between the patient and provider within this field. For example, some commentators have critiqued programmes that have sought to push the uptake of LARC methods among groups considered high-risk for unplanned pregnancy as being exploitative of their vulnerabilities and undermining of the agency of these individual women (251, 252). Another area with potential for power struggle is where ambivalent feelings about pregnancy lead to ineffective contraceptive practice which may be at odds with provider advice, but aligned with women's perceptions of their own motivations and requirements (253-257). Ambivalence about pregnancy and contraceptive method choices (145, 146) as well as outcomes relating to effective use of contraception (54, 256) and unplanned pregnancy (1) have all been associated with social class and other sociodemographic factors.

3.4.3 Health Inequalities in Contraceptive Practice

Abel & Frohlich (2012) used Bourdieu's Theory of Practice to highlight how the unequal distribution of capital and the unifying and reinforcing power of habitus can lead to persistent health inequalities (214). Health inequalities in contraceptive practice are evident from the observational studies discussed in Chapter 2. Wellings et al. (2015) found that, among 893

women of reproductive age, non-use of contraception was associated with the absence of educational qualifications, being economically inactive and smoking and drinking (145). Other studies analysing NATSAL-1 data have shown that contraceptive use is significantly lower in all ethnic minority groups than in women of white ethnic group (8) and that socioeconomic characteristics are determinants of contraceptive use operating at the individual and area level with area disadvantage associated with lower likelihood of use (54).

Such outcomes may be indicative of habitus and the accumulation and dispensation of relevant capital whereby effective contraceptive practices become the product of particular social groupings (226, 239). However, Bourdieu stressed that the social world is not easily collapsed into the distinct social categories employed by most quantitative research (258). The latter study by Bentley et al. (2009) which indicated that contraceptive practice is associated with the area in which women reside as well as their personal circumstance stressed the need for further qualitative research to develop understanding of these links. However, there remains a dearth of qualitative inquiry in this area of health inequality in the UK. Qualitative studies around contraceptive practice focus on generational societal groupings and report the views of young people.

Pregnancies which occur among adolescents and young adult women are commonly reported as unplanned (1) and much qualitative research has been directed towards understanding what influences the decision-making among this high-risk group. Baxter et al.'s (2011) systematic review and thematic synthesis of views about contraceptive service delivery among young people in the UK found that use or non-use of contraceptives was related to risk perception in addition to attitudes towards the outcome of pregnancy and variation in the positive and negative perceptions of different forms of contraception (259). The study reported that friendship groups, peers, parents and partners can impact attitudes towards contraception with friendship groups described as a "key source of advice and information". This corresponds with Abel & Frohlich's (2012) discussion of health inequalities being the result of health-relevant cultural capital that can be "accumulated over time in individuals, families or peer groups through personal and collective investment such as social and cognitive learning, social exchange and support, all often part of individual's life long socialisation" (214).

Baxter et al.'s (2011) review also commented on ethnicity, highlighting where differential outcomes were noted according to the ethnicity of the participants, such as the finding that young people of African and Indian ethnicity perceived contraceptive services from GPs to be lacking in confidentiality (259). Whilst there is a lack of qualitative research focusing on ethnicity and contraceptive use and access, there have been several that have focused on ethnicity and sexual and reproductive health risk (260-265). These demonstrate that discrete categories of ethnic groups are likely to over-simplify the complex array of factors that mediate associations of ethnicity and poor sexual health outcomes which include cultural factors (261, 262), religious factors (260, 263), differences in parental attitudes (265), peer-group norms, gender roles and socioeconomic determinants (264). With regard to health care access, it has been posited that

ethnicity is a form of habitus, centralising on the idea that ethnic, and by extension, cultural differences may be an important dimension within wider societal power relations which may disadvantage BAME groups in accessing services and interacting with healthcare professionals (266). However, this too may be a simplistic consideration of ethnicity, falling prey to the fallacy that there is a fixed and homogenous notion of culture pertaining to each ethnic group (267).

Bourdieu was critical of logic that divided society by sociodemographic groupings based on age or ethnicity, arguing that these could not be powerful enough alone to transverse class divisions (268, 269). This tendency to subsume distinctions of gender, age and ethnicity into his broad notions of social class and capital distribution has been critiqued by Hall (1992) as being reductive of the dynamics of social groupings and the power of cultural capital to accumulate in ways which may overlap or contradict purely class-based divisions (270). However, a strength of Bourdieu's theorising is in differentiating between states of capital, including that which is economic, social and cultural, with the emphasis on the composition of one's overall capital and how it is employed and relationally bound with habitus and field. Therefore, Bourdieu's capital has the capacity to be applied in a way which is cognisant of the complexity and dynamism of social groupings, acknowledging generational unity within specific fields and the potential power of ethnicity to effect dispositions and opportunities (271, 272). In "The Social Space and the Genesis of Groups" (1985) Bourdieu stated that "the most objective differences may be marked by more immediately visible differences" than class alone (229).

The discussion of health inequalities emphasises that although the contraceptive consultation is the embodiment of the contraceptive field, the accumulation of capital and the unifying and reinforcing power of habitus are dynamic and active components of Bourdieu's formula:

[(habitus) (capital)] + field = practice.

They involve processes and social interactions that take place beyond the field of the patient-provider consultation. Thus, contraceptive practice is influenced by factors within but also beyond the consultation and as such, even in a context of free access to contraception, health inequalities can remain entrenched. Investigation of these factors is often motivated by a desire to understand how to address these inequalities. Interventions that seek to improve contraceptive practice very often target groups at high-risk of unplanned pregnancy or similar contraceptive outcomes, such as the remote and digital counselling interventions discussed in section 2.8.

3.4.4 Conveying Capital through Remote and Digital Counselling Interventions

Remote and digital contraceptive counselling interventions are a growing area of research, taking advantage of the ubiquity of internet-enabled devices and near universal mobile phone ownership (31) to deliver contraceptive advice, information and support (32-35). In section 2.8, these were divided into digital decision aids and interactive computer-based interventions (ICBIs), phone call support and text messaging interventions. ICBIs are considered effective tools for conveying sexual health information with positive effects reported on outcomes of

sexual health knowledge, self-efficacy and sexual behaviour, although there is little evidence on their effectiveness on outcomes more specific to contraceptive access and use (164). Contraceptive digital decision aids are interactive tools which convey tailored information and advice to people pre-consultation, when they are considering their contraceptive needs (165). Research on these also remain limited, although the UK decision aid *My Contraception Tool* has been very popular and positively received (36). Phone calls to enhance contraceptive counselling post-consultation did not positively impact adherence, uptake or use with one study failing to fulfil the protocol in terms of number of phone calls to the intervention group due to inability to reach participants (174). There were mixed results from interventions that used text messaging with a review stating broadly promising effects on contraceptive use and adherence from 5 RCTs, although authors remained cautious as the evidence on longer-term effects, particularly on the outcome of unplanned pregnancy, are yet to be firmly established (32).

Considered through a Bourdieusian lens, these interventions are used either pre or post consultation to extend the field of contraception beyond the traditionally conceived face-to-face patient-provider interactions that take place within clinical environments into the day-to-day decision-making that constitutes contraceptive practice. This is in line with the Bourdieu's arguments against dichotomies. Structure and agency are shown to be dialectic as the information and guidance from the provider helps to shape patient agency. For example, digital decision aids may be effective via the mechanism of conveying capital in the form of contraceptive information prior to the consultation, which could potentially redress the power imbalance in the contraceptive field, enhancing patients' capital in the form of contraceptive knowledge and increasing their capacity for agency in their contraceptive choices (216, 235).

However, whilst internet access is near universal in developed settings, the capacity to effectively engage with online health information is still subject to inequalities. Health-related internet use has been explored using Bourdieu's concept of habitus (273). Hale posed the idea of an "Internet habitus" as the precursor and product of the social and structural conditions that impact the self-efficacy to navigate and acquire relevant, online health information. Like other forms of habitus, this practice is inherently social, leading to the accumulation and exacerbation of existing inequalities. This form of self-efficacy could be thought of as e-health literacy, which is defined as "the ability to seek, find, understand and appraise health information from electronic sources and apply knowledge gained to addressing or solving a health problem" (274). The association of high e-health literacy with being younger, better educated and an active consumer of online information (275) further substantiates Hale's Internet habitus as a driver of socially patterned health outcomes. Thus, before conclusions can be drawn about the potential for contraceptive digital decision aids to positively impact contraceptive health outcomes, further research is required to establish how they can be effectively accessed and used by those who may be doubly disadvantaged by both increased likelihood of poor contraceptive health outcomes and an Internet habitus that is a product of socially and structurally driven disparities in e-health literacy.

3.5 Application of the Theoretical Framework to the Online Contraceptive Service

The intervention under investigation in this thesis is novel with no precedence in the literature of direct relevance to this platform of contraception delivery and its position within the UK health system. Therefore, the theoretical framework enables a more abstract consideration of the extent to which this could alter traditional models of contraceptive provision. This Bourdieusian perspective reconfigures the intervention of online contraception as a structural shift in provision and alteration in the field of contraceptive healthcare that could fundamentally alter the power dynamics involved in the interaction between a service-user and provider, giving contraceptive service-users in Lambeth and Southwark greater agency in terms of access to information, but also greater choice in terms of the mode of access to OCPs and the option to communicate with their contraceptive provider using remote modes of communication including text messaging. However, consideration of the online service is incomplete without appreciation of its positioning within a wider landscape of providers and the relative forms of capital and habitus required for effective access within different types of services. Furthermore, the capacity for habitus to engender homogeneity in social groups and the nature of capital to be unequally distributed in society raises the question of whether the introduction of online contraception into this wider landscape of providers could serve to alleviate or exacerbate health inequalities in effective contraceptive practices.

Unlike the digital and remote interventions discussed in the literature, the online contraceptive service includes the home delivery of OCPs. This is of critical importance because, rather than supplementing or directing patients to face-to-face consultations to obtain their method of choice, the online service could in fact supplant a face-to-face interaction all together. Such fundamentally enhanced patient agency and alteration of the patient-provider interaction to the extent that it is entirely remote and digitised could be perceived as advantageous, particularly for those who experience barriers to face-to-face services.

Negotiating barriers to access physical services for contraception is a type of practice in itself; where each service-type can represent its own unique field, encompassing a certain social space and network of relations. It was discussed in Chapter 2 that disinvestment in contraceptive provision, coupled with intensifying demand has contributed to long waiting times in walk-in SRH services and difficulties in getting appointment at general practice. Accessing general practice requires one to be registered at a service, have the organisation and preparedness to schedule appointments in advance and skills in communication to acquire what is needed from staff, both clinical and administrative. Whilst walk-in services do not require patients to be registered, women may still benefit from having knowledge of opening times, optimum times to attend to maximise the possibility of being seen, and skills in how to communicate their needs to staff members. Attendance at all types of face-to-face providers requires the ability to use transport or walk to the service and time to attend, which can be challenging as opening times often conflict with working hours and educational or other commitments. Studies considering remote consulting and home delivered medication in general

healthcare stress the benefits in terms of convenience; saving patients' time and removing geographical barriers (276). A review of studies examining the effect of the number of OCP packs prescribed have highlighted that the need for regular visits to contraceptive providers to replenish supplies may serve as an impediment to continuity (277). Whilst SH:24's online service does not extend pack supply relative to traditional providers, arguably, the relative convenience of ordering online is comparable to receiving a lengthy supply; removing the need for physical attendance at a service. Therefore, it could be posited that providing the option to replace physical access with an online service, enhances choice to those without the habitus and capital that is necessary for effective access within physical services which could serve to improve their contraceptive practice.

It is also important to consider what may be lost should face-to-face access be replaced with the online service. In section 3.4.2 the power dynamic within the patient-provider interaction was discussed with emphasis on the provider's dominant form of cultural capital with regard to both professional status and the relevant medical knowledge and expertise. To replace face-to-face consultations in contraceptive provision may be detrimental, leading to the loss of the conveyance of capital such as advice around side-effects or the promotion of alternative methods. Furthermore, whilst the online service provides information on all contraceptive methods available in the UK, it can only provide access and home delivery of one brand of POP and one brand of COC. This could be viewed as choice-limiting and thus diminishing of patient agency; giving the provider power to dictate contraceptive method by virtue of the absence of alternatives.

Conversely, there are elements of more supportive care that maintain, or perhaps even strengthen the dialectic interplay in the patient-provider interaction by extending communication beyond the consultation. Text messaging, which the literature indicates is a promising avenue to enhance contraceptive practice, can influence routinised, day to day decision making and potentially surface this practice above a myriad of other competing issues in the lives of the patient. Through providing supportive provider contact beyond the consultation, the text messaging interventions help to account for the complexities of contraceptive decision-making that extend into everyday life, particularly for methods like OCPs which require daily adherence. Depending on how text messaging is employed by the online intervention, this may be an important active component in generating positive health outcomes for the target population.

In section 3.4.3 the capacity for habitus to engender homogeneity in social groups and the nature of capital to be unequally distributed in society was discussed in terms of health inequalities in effective contraceptive practices. There also appears to be a degree of homogeneity within social groups in terms of their contraceptive service access with French et al.'s (2017) analysis of NATSAL-3 data suggested that community clinics are more commonly used by women in living in urban areas, women living in more deprived areas and women in black and other ethnic minority groups whilst general practice was used by fewer women aged 16-17 years compared to older age groups (70). In the light of the discussion around digital

decision aids (section 3.4.4), it may be the case that there are also societal aggregations in terms of which members of the population use the online service. This may be related to Internet habitus with societal divisions in access delineated according to who has the e-health literacy to actively seek out and effectively use the online service.

Another possibility is that the online service is not seen as an alternative to existing providers such as general practice and community clinics, but rather as one further option introduced into the contraceptive field. This may mean that service-users navigate within and between their different provider and method options depending on their circumstances and preferences in a way which is ultimately choice-enhancing; for example, using the online service for temporary access to OCPs and then switching to a clinic service to obtain LARC. However, even when viewing the online service as an additional option of access within the landscape of providers, there are concerns about the extent to which capital, in terms of the knowledge and skills to ascertain the most appropriate and effective provider for a given requirement, may be unevenly distributed across society. Thus, a potential outcome of introducing the intervention into the existing landscape of contraceptive providers is that only those of a habitus and with the capital to access a range of providers, such as e-health literacy to access OCPs online and knowledge of their local face-to-face services, would be in a position to benefit from overall enhanced choice.

3.6 Application of the Framework in this Thesis

This chapter has presented an overarching theoretical framework, using selected concepts from Bourdieu's immense body of work as the lens through which to consider contraceptive decision-making and activities as a unique practice and then, to reflect on online contraception as a fundamental shift in provision that may have profound implications for this practice. This, in conjunction with the narrower, theory of change conceptual framework in Chapter 4 will enable both a context-specific appreciation of the empirical findings but also a more abstract interpretation and contextualisation within broader society.

Rather than attempting to fit empirical findings into a social cognitive model focused on socio-medical discourse as the arena of change, the Bourdieusian approach facilitates a more expansive interpretation and allows reflection on the multiple, interlinked and complex factors that constitute contraceptive decision-making. In particular, Bourdieu's concept of habitus facilitates understanding of the complexities of contraceptive practice, encompassing the myriad influencing factors including individual attitudes, temporal circumstances and values that extend beyond the traditionally conceived of patient-provider interaction.

In addition, a Bourdieusian ontological position is apt as the empirical studies in this thesis are both qualitative and quantitative in nature and thus require an approach that transcends the objectivism/subjectivism dichotomy. Bourdieu's research paradigm of "reflexive sociology" based on his "constructivist structuralism" epistemological approach (278, 279) encompasses

the subjective perception, thought and action which are borne of the habitus as well as the objective structures which are independent of the subjective consciousness of agents and which shape practice. The mixture of data sources employed in this thesis, including self-reported survey data, semi-structured interview data and objective, routine service data can be appreciated collectively with this paradigm. Crucially, it also facilitates greater understanding of the limitations of this data and what further research is required to develop the knowledge base of this, and similar interventions, primarily within the final discussion chapter (Chapter 8).

3.7 Summary of Chapter 3

- The wider theoretical basis of this thesis has been presented, using selected concepts from Bourdieu's body of work to consider contraceptive decision-making and activities as a unique practice. This framework facilitates understanding of the interplay of agency and structure in contraceptive decision-making, the power dynamics involved in patient-provider relationships and the health inequalities apparent in contraceptive outcomes across populations.
- Contraceptive practice involves day-to-day, routinised decision making which is generated by habitus, with access to supplies and information requiring interaction with health professionals within the field of contraceptive healthcare - an interaction which requires contraceptive-users to deploy and possibly acquire forms of capital, such as the knowledge and skills to choose and access a contraceptive method that is appropriate and effective.
- This Bourdieusian perspective reconfigures the intervention of online contraception as a structural shift in provision that could fundamentally alter the power dynamics involved in the interaction between a service-user and provider in the contraceptive consultation process, giving contraceptive service-users in Lambeth and Southwark greater agency in their contraceptive practice, specifically in relation to access and use of OCPs. Positive effects could be contingent upon the expenditure of capital and the habitus required for effective access within the wider landscape of provision; with the capacity for habitus to engender homogeneity in social groups and the nature of capital to be unequally distributed in society raising the question of whether the intervention could serve to exacerbate health inequalities in effective contraceptive practices.
- A Bourdieusian ontological position that transcends the objectivism/subjectivism dichotomy provides a suitable research paradigm through which to appreciate the mixed methods empirical approach of the thesis.

4 Developing a Conceptual Model using a Theory of Change Approach

4.1 Chapter Overview

Chapter 3 applied Bourdieu's Theory of Practice to frame contraceptive decision-making and activities as a unique practice and to develop a sociological understanding of the potential impact of online contraception on this practice. Whilst this overarching theory will facilitate the abstraction of findings beyond the stated context; a context-specific framework is required to conceptualise the internal processes of the change generated by the intervention within the target population and to identify key questions for its evaluation. This chapter is the first empirical study of the thesis; using qualitative methodology, informed by the literature on theory-driven evaluation, to generate a conceptual model of the impact of the intervention.

4.2 Background and Rationale

SH:24's online contraception service is of the scope and scale to be considered a complex intervention, thus the evaluation strategy is informed by the guidance and literature available for such interventions, which recommends the development of a conceptual model that is centred on a reflective and realistic approach (280, 281). The Theory of Change (ToC) was originally developed to evaluate "Comprehensive Community Initiatives" (CCIs), which are multi-layered, inter-disciplinary strategies to improve conditions in communities (282-284). Although this online contraception intervention is more health-focused than traditional CCI definitions, it has similarities in its multi-stranded approach to affect change.

The ToC approach is one of many discussed in the literature on Theory-Driven Evaluation (TDE). The development of TDE was motivated by the limitations of traditional method-driven evaluation approaches to provide conclusive results on efficacy and effectiveness for complex interventions (285, 286). TDE views effectiveness as reflective of the stated points of importance in the intervention with outcomes that clearly connect to the activities initiated by the intervention (285). In order to achieve this, the evaluator pursues the unravelling of the relationships between context, content, application and outcomes (287). TDE also shifts the role of the evaluator from a passive and separate information-provider to an active stakeholder in the programme who can usefully contribute to the decision-making process (288, 289). TDE aims to have both external and internal validity (290): internal validity to prevent understanding of the effectiveness of the intervention being confounded by correlations between the treatment and extraneous variables (285); and external validity to explain the interplay between the context, the intervention and its effects (283, 291).

A popular alternative to ToC is Realistic Evaluation (RE) (291). Both the RE and ToC approaches are centred on using the theory of the intervention to inform the purpose, focus and pertinent questions of the evaluation (292). However, the ToC approach was deemed more suitable for this thesis as it positions the evaluator as an active stakeholder in the intervention

(293). Secondly, the RE approach gives precedence to external validity through the cumulative process of theory building whereas the ToC approach gives the evaluation the flexibility to integrate methods that maximise internal validity (290).

According to Weiss (1995), the ToC approach encompasses the idea that an evaluation should be based on the "theories of change that underlie the initiatives" or in other words, it should ask, "how and why does an initiative work?" (283). Integral to this is the process of surfacing and exploring the assumptions that underlie how the inputs of the intervention lead to the outcomes or responses from the target population (283, 289, 290, 294, 295). Assumptions are propositions that are taken for granted and can be representative of peoples' values, ideological perspectives and expectations. These assumptions are usually implicit; in other words, they are the *perceived* components of the "Black Box" (294). The "Black Box" leaves opaque the processes which exist between inputs of the intervention and the outcomes (296). According to Weiss (1997), the "evaluation needs to get inside the black box" to uncover the assumptions that are the drivers of the intervention design (289).

SH:24 takes an agile and iterative approach to intervention design that is responsive to service-user demand and shifts in the context of contraceptive provision (297). The evaluation seeks to be reflective of this design approach in order to inform the development of the intervention (281, 298). In addition, an online contraception service of this complexity and scale and with relevance to a UK context is not reported in the literature. Therefore, a ToC conceptual framework is most appropriate to conceptualise the internal processes that could be initiated by the intervention and its localised impact on the target population for the identification of key questions for its evaluation.

4.3 Aims and Objectives

The ToC is captured as a model and a narrative summary that aims to strengthen the effectiveness of the evaluation and intervention design. Central to this is the explication of the assumptions underlying the cause-effect relationships between inputs and outcomes. Critical reflection of the positive processes of change depicted in the ToC model, and the assumptions that underpin them, reveal the pertinent questions of the evaluation.

4.4 Research Questions

This is an exploratory, qualitative study that seeks to articulate the theory underpinning the intervention through consideration of the following research questions:

- What do stakeholders perceive as the pivotal inputs that will generate change in the target population?
- What are the proximal and distal outcomes that the intervention seeks to achieve?
- What do stakeholders perceive as the relevant contextual factors?
- How do stakeholders think the target population will respond to the intervention?

- What are the assumptions underlying the positive processes of change between the intervention inputs and the intended outcomes?
- Do stakeholders predict any potential risks or negative processes of change?

4.5 Methods

Mason and Barnes emphasised that the ToC approach requires collaboration from the outset to be grounded in the views of the stakeholders (293). They specify stakeholders as those who were involved in the programme when it was conceived, as well as management personnel and frontline practitioners and service-users. Three data sources were chosen to encompass a range of stakeholder viewpoints as recommended.

4.5.1 Data Sources

1) SH:24 Programme Funding Application

The SH:24 original programme funding application was produced by the programme developers in collaboration with Lambeth and Southwark's public health departments and NHS foundation trusts. It was produced two years into the service's inception and was successful in securing funding from Guy's & St. Thomas's Charity for the launch of a 4 year programme in 2013. It was a key source to determine the origins and development of the causal model to determine the implicit reasoning behind the proposed service activities (including the perceived aetiology of the problem) and the intended outcomes (293, 294).

2) Secondary Data: Transcripts of Interviews for Related ToC Study

Between 2013 and 2014, the SH:24 evaluation research group at KCL (within which I sat as a PhD student) conducted 14 interviews with a range of stakeholders for a study published in 2015, "How online sexual health services could work; generating theory to support development" (195). They sought to articulate a broad theory of change for the whole SH:24 service. However, this period of SH:24's development was highly focused on the STI testing component of the service. This was reflected in the study's findings which largely overlooked the proposed contraceptive elements. The lead author of this research, and the primary supervisor of this thesis, Dr Paula Baraitser (PB), provided me with these transcripts for re-analysis with a focus on the findings that had relevance to contraception. Further details about participants are in Table 4-1.

3) Primary Data: Seven Supplementary In-depth Interviews

From late 2014 until early 2015, I conducted in-depth interviews with a supplementary sample of seven participants (Table 4-1). This was added to the existing sample of 14

interviews to ensure sufficient data for analysis of themes relevant to the contraceptive component of the SH:24 service.

4.5.2 Sampling and Recruitment Procedure

A purposive sampling procedure was used to obtain a sample that had expertise in sexual and reproductive health (SRH) services or online health services available to Lambeth and Southwark residents. They were also sampled for their heterogeneity in terms of the nature of their interaction with services, for example, some participants were SRH service-providers whilst others were service-users. In addition, they were sampled for their heterogeneity in terms of their proximity to the development of the online service, ranging from the inner circle of stakeholders who had direct involvement with development, to those who lived and worked in the target area and who's professional work or service-access would be impacted by the intervention.

Members of the SH:24 evaluation research group (myself included) were also stakeholders in the SH:24 programme, both directly embedded in the development of the intervention, but also as professionals who had worked within SRH services in Lambeth and Southwark, either during the time the research was conducted, or at some point within the previous five years of data collection. This meant that the participants most suitable for the study could be recruited through professional connections. The head of the SH:24 evaluation research group at KCL, PB, held various positions of relevance to the study, including Director at SH:24, GUM consultant at Camberwell Sexual Health Centre and member of the Faculty of Sexual & Reproductive Healthcare (FSRH). Therefore, the majority of the 21 participants were recruited via PB's connections. I had a number of relevant connections having previously worked as a receptionist, client support worker and health promotion specialist in SRH services in and around the Lambeth and Southwark area prior to my position as PhD student, thus some participants in the supplementary sample were recruited via these connections.

Due to the nature of the relationships between the researchers and the participants, the recruitment procedure typically involved an initial, informal conversation, via email, phone or in person to find out if the person was interested. This was followed up with a formal email (Appendix H) stating the purpose of the study and some brief details about what participation would involve, including the participant information sheet (Appendix I) as an attachment. The participant could then decline, request further information or agree and arrange a suitable time and place to conduct the interview in the following few weeks. Three individuals approached for an interview either did not reply or were unable to find a time in their schedule to meet. Researchers expressed to the participants that the interview should take place at their convenience, at a place and time that was suitable for them, provided the venue was private and quiet. Several interviews took place in the work places of the participants and some took place in a private room in Camberwell Sexual Health Centre (CSHC) or in the Weston

Education Centre, part of the KCL Denmark Hill campus where the SH:24 evaluation research group was based.

Table 4-1 Description of Sample

Participant Number	Stakeholder Type	Level of involvement	Further relevant characteristics
Secondary data source: initial 14 interviews			
1	Public Health Executive	Indirect, external to programme	- Female - Involved in commissioning at a senior level within the target area for several years
2	Director of an Academic Health Science Centre	Indirect, external to programme	- Female - Involved in non SRH digital health services development
3	Healthcare Commissioner	Indirect, external to programme	- Female - Senior commissioner within target area
4	Senior Manager within Clinical Services	Indirect, external to programme	- Female - Involved in provider management in NHS Trust within target area
5	Senior Manager within Clinical Services	Indirect, external to programme	- Male - Involved in provider management in NHS Trust within target area
6	Senior Manager within Clinical Services	Indirect, external to programme	- Male - Involved in technical infrastructure of clinical services
7	Senior Nurse in SRH Services	Indirect, external to programme	- Female
8	Senior Consultant in SRH Services	Direct, internal to programme	- Male - Involved in the development of various digital and online SRH services including this programme
9	GP within target area	Indirect, external to programme	- Female - SRH lead
10	Client Support Worker	Indirect, external to programme	- Male
11	Service-users of local SRH services and potential service-user of SH:24	Indirect, external to programme	- Male - MSM
12	Service-users of local SRH services and potential service-user of SH:24	Indirect, external to programme	- Female - BAME - Local resident
13	Service-users of local SRH services and potential service-user of SH:24	Indirect, external to programme	- Female - BAME - Local resident
14	Service-users of local SRH services and potential service-user of SH:24	Indirect, external to programme	- Female - BAME - Local resident
Primary data: supplementary sample			
15	Developer of online SRH services for target population	Indirect, external to programme	- Female - Previously worked for a national provider of online health services
16	Public health registrar working within target area	Indirect, external to programme	- Female - Contraceptive service-user - Previous involvement in pharmacy provision of contraception
17	Senior manager of SRH services for target population	Some limited direct involvement through seat on board of external stakeholders	- Female - Member of board of external stakeholders of online service
18	Senior outreach worker in target population	Indirect, external to programme	- Female
19	Senior contraceptive nurse	Indirect, external to programme	- Female - Previous involvement in online SRH services - Reproductive health researcher
20	Reproductive health consultant	Indirect, external to programme	- Male - Consultant for private, online contraceptive service
21	Public health registrar and researcher of online health	Direct involvement with programme through research activities	- Female - Safeguarding expert

Sexual and reproductive health, SRH; general practitioner, GP; men who have sex with men, MSM; black, Asian and minority ethnic, BAME

4.5.3 Conduct of Interviews

With regard to the secondary data source of the initial 14 interviews, information on the conduct of the interviews was provided by the lead author (PB) and one of the co-authors, Jonathan Syred (JS) of the original publication (195). All interviews were conducted in person and recorded using a tape recorder. Participants were shown the participant information sheet again at the start of the interview and were then asked to read and sign the consent form (Appendix J). Interviews were conducted with any of three authors of the publication, including PB and JS, and on occasion, with two or all three in the room. Interviewers listed inputs of the online service on a large sheet of paper and suggested outcomes and processes which were documented on this diagrammatically throughout the interview as responses were provided. The interview guide for these 14 interviews is presented in Table 4-2.

Table 4-2 Interview Guide for Initial 14 Interviews with Online Services Stakeholders

- Could you please start by telling me how such a service might have an impact on the health of the population of Lambeth and Southwark? (Prompt for multiple impacts and list these as outputs on the diagram*)
  - If we do x then y will result because…
  - *Document links between inputs and outputs using process mapping and keep asking*, "and then what happens?"

- Taking each impact individually and repeat the following questions for each one – summarising the answers on the diagram as you do so:
  - What things would need to be in place for this impact to happen? *List inputs on diagram)*
  - If these things (inputs) were in place how would they cause the impact that you have described?
  - What assumptions have you made in describing this link between the inputs and the impacts?
  - What things could prevent these inputs leading to the impact that you have described?
  - What things might help them to happen as you have described?

- The links between inputs and impacts that you have described above, would they be linked in the same way for all of the different populations in Lambeth and Southwark?   - *Prompt specifically for young people, BAME groups, MSM, people from your community, "someone like you"*
- What external influences (outside the scope of the project) might be important in influencing whether the project had the impacts that you have described?

- *Questions for defining programme theory:*
  - *Aim*
  - *Target Population*
  - In what ways/ in what settings will the programme operate?
  - What the prevailing theories about why it will work?

Men who have sex with men, MSM; black, Asian and minority ethnic, BAME

I conducted all seven supplementary interviews. Prior to interviewing the participants, I conducted a mock interview with JS, in order to refine my technique through practice and to gain critical feedback from a researcher who had been directly involved in the original interviews and ToC publication (the data from this interview was not used). Following the protocol in the original interviews, participants in the supplementary sample were reminded of the participant information sheet that they had been previously emailed at the start of the interview and were then asked to read and sign the consent form (Appendix J). All interviews were recorded using an Apple MacBook Pro laptop (2014).

The interview guide for these additional interviews is presented in Table 4-3. After the initial "warm-up" questions: "could we start off by hearing a little about your experience in or with contraceptive health services?" and "do you have any knowledge or expertise around online health services in general?" – I read a short statement to orient the participant; explaining what the purpose of the interview was and providing some suggestions about what the online contraceptive service could potentially involve. These elements were printed and shown to the

participant during the interview to act as a prompt for the rest of the discussion (Figure 4-1). During the time that these interviews were conducted, the online service was in a very early stage of development and it was not yet known what methods of contraception would be available to service-users or the precise mode of delivery, thus the interview guide and the elements in Figure 4-1 contained a vague outline of potential elements of the service, gleaned from analysis of the SH:24 programme funding application, to which the participants could provide an opinion to inform the development of the final ToC model. Apart from this introductory section towards the beginning of the interview, the guide helped to prompt the discussion, but was not used prescriptively. Interviews were semi-structured to allow exploration of themes arising according to the expertise, knowledge and experiences of the participants.

Table 4-3 Interview Guide for Supplementary Sample of External Stakeholders

- Could we start off by hearing a little about your experience in or with contraceptive health services?
- Do you have any knowledge or expertise around online health services in general?
- This interview is about understanding the impact of online contraceptive health services on the population of Lambeth and Southwark. The service will allow people to access contraception from the NHS by logging onto a secure website, completing a risk assessment and ordering contraception. The types of contraception that could be available are: o Combined oral contraceptive pills o Progesterone only contraceptive pills o The patch o Injectable contraception o Condoms o Advanced provision of emergency contraception o Retrospective provision of emergency contraception o Pregnancy tests These can be picked up from the clinic without having to see a health professional or they can be picked up from a pharmacy or sent to the person's home. Some aspects may need more physical interaction with services than others, e.g. obtaining COC would require providing a BP measure. There will also be a support service in addition to the website offering interactive advice and links to existing services, e.g. advice about the implant and where to go to get it.
- Could you tell me how internet-based contraception from SH:24 might have an impact on the health of the population of Lambeth and Southwark?
- What assumptions have you made in describing this link between the inputs and the impacts?
- What will be the negative and positive outcomes or impacts of an internet-based contraception service?
- What things might help these outcomes happen as you have described?
- In terms of the pathway between inputs and impacts that you have described, would this be the same for all the different groups and communities in Lambeth and Southwark?
- What factors outside of the scope of SH:24 might be important in influencing whether the project has the impacts that you have described?

National Health Service, NHS; combine oral contraception, COC; blood pressure, BP

Figure 4-1 Interview Prompting Tool

4.5.4 Interviewer Effects

The following effects are a product of my own reflective process as the interviewer of the supplementary sample. These effects may also have influenced the nature of my analysis and interpretation of all data sources.

Age. Although I did not ask for the dates of birth of any of the participants, it was apparent that I was younger (aged 27 years at the time of the interviews) than at least five of the seven participants. In some cases, I felt that this helped to put participants at ease, enabling them to speak freely and authoritatively on the topics. Conversely, it is possible that participants made assumptions about my lack of experience or knowledge of the topics discussed, preventing them from delving into the complexities and nuances of the points mentioned.

Gender. Only one of the additional seven interviewees was male. As the interviewees were largely based on opinions based on professional experience and expertise, my gender felt largely inconsequential. However, a surprising outcome of the interviews was that, on occasion, the female participants volunteered information about their own, personal, contraceptive experiences. It is possible that these participants felt comfortable talking to me about these experiences as I am a female of reproductive age who is quite likely to have had my own experiences with accessing contraceptive methods and services.

Pre-existing professional relationships. I had worked with two of the participants in previous job roles which I felt positively impacted the interview process, allowing a more rapid transition into a comfortable and in-depth discussion. One of these had been rather more senior than me in this previous role which may have encouraged me to be more formal and deferential during the conduct of this interview. One of the participants was in the same research team as me during the time of the interview. That I had previous or current professional relationships with some participants, whilst others were people I had not previously met, may have differentially affected the collection and interpretation of results across the sample.

Professional status. As a PhD student, my professional status may have been deemed as relatively junior, particularly when compared to those participants in very senior roles. This may have impacted the interview process in a similar way to age. The other main issue was that as a PhD student of one of SH:24's Directors; a member of the SH:24 evaluation team and a recipient of a studentship awarded as part of an SH:24 grant from Guy's & St.Thomas' Charity, some participants may have perceived me as a representative of SH:24 and may have felt biased towards discussing SH:24 more positively.

As I was not involved in the conduct of interviews for the original 14 interviews, it is not possible to explore the interviewer effects that may have influenced the collection of this data. Considering the publication by Baraitser et al. (2015) (195), analysis of the transcripts and personal communications with two of the authors of this study who also conducted the majority of these interviews (Baraitser P and Syred J 2015, oral communication, 10th October), it is likely that the interview effects at play were very different. For example, PB occupies more senior positions and is of a higher professional status compared to me, so any pre-existing or current professional relationships with participants would have likely had a very different dynamic. All interviewers were members of the SH:24 evaluation team so may too have been perceived as SH:24 representatives, thus could have been subject to a similar bias towards a positive consideration of the impact of the service as those in the supplementary sample.

4.5.5 Analysis

A three stage inductive, qualitative analysis was conducted using a framework approach (299) with the qualitative analysis software NVivo (NVivo; QSR International Pty Ltd. Version 10, 2012). Analysis took place in subsequent stages so that findings from each data source could help to build and refine themes for the final ToC model and narrative. At each stage the goal was to identify the important elements of the intervention, describe all possible outcomes and the assumptions underpinning these processes of change.

In stage one the programme funding application was read and re-read to establish the components of the planned intervention, the outcomes and intentions articulated in the document with relevance to the contraceptive components and any additional detail about the mechanisms of change. This provided a rudimentary theory of change framework. In stage two

all data on the online contraceptive service from the transcripts of the first 14 interviews were analysed by myself and PB. Initially, data were coded according to the framework generated in stage one, followed by a more inductive approach to determine new themes and to generate initial process diagrams describing the proximal and distal outcomes of the intervention and the causal mechanisms through which they were expected to be achieved. The themes emerging from this analysis were tested and refined in the final seven interviews that focused on the contraceptive service only. The themes also shaped the interview guide for the supplementary sample (Table 4-3) and the figure of suggested inputs that was presented to the participants (Figure 4-1).

I transcribed all interviews in the supplementary sample which was helpful in familiarising myself with the data. These were also read and re-read and then added to the whole dataset for stage three, the final thematic analysis. Index categories were already established through stages one and two of analysis, so initially the final dataset was coded accordingly. However, the supplementary dataset was also inductively analysed to further refine themes and add new index categories. Thematic charting was conducted to synthesise the essential elements of all the data sources and place it within the final thematic framework. The framework formed the basis for the generation of process diagrams which went through several iterations until the final ToC model was produced. This was a non-linear process requiring repeated reviewing of the data and adjustment of the model to achieve increasing parsimony with each iteration. PB and ER's PhD second supervisor, Professor Caroline Free (CF) were consulted at each stage of this process, verifying the codes, reviewing the charted data and each of the process diagrams.

4.5.6 Ethical Considerations

Participants' consent was on the basis of confidentiality and anonymity in the publication of data. Care has been taken to protect the identities of participants in the description of the sample and in the quotations presented. Identifiable information has been stored securely and separately from interview data. Ethical approval for this research was granted by King's College London research ethics committee (Ref: BDM/13/14-42) (Appendix T).

4.6 Results

4.6.1 The Theory of Change Conceptual Model

The final ToC conceptual model is presented in Figure 4-2. It depicts the positive processes of change that stakeholders predicted could be initiated through the introduction of online contraceptive services in Lambeth and Southwark. It suggests that the ultimate outcome of a reduction in rates of unplanned pregnancy could be achieved by improving contraceptive continuation and uptake through three proximal outcomes: 1) increased convenience and anonymity in access to contraceptive supplies; 2) greater autonomy in contraceptive decision-making via online information and the online consultation process; and 3) access to more

responsive provider-support to maintain service-users' access to a range of contraceptive methods and therapeutic care (Figure 4-2).

This final ToC conceptual model was the end product of several iterations of the design based on incremental understanding of the data at each stage of analysis. A vital stage in this process came after the initial programme funding application and the initial 14 interviews had been analysed, which led to the design of two theory of change models, which can be seen in Appendix K. These split the models according to positive and negative processes of change, distinguishing between the beneficial impacts and the risks of the intervention that had been articulated by participants. After the addition of the supplementary sample to the dataset, and the final stage of
analysis, it was possible to combine and simplify these models. The models were refined in the following ways:

1. ***Greater focus on the assumptions of the model.*** This negated the need for both positive and negative models by asserting that any process of change for such an innovative service would be based on assumptions. Assumptions were centralised in the final model and explored further in the narrative. The narrative allowed consideration of the more nuanced predictions made by stakeholders, including the potential risks and downsides of the intervention. Furthermore, these assumptions were focused on how the target population would respond to the inputs of online contraception, therefore encompassing key contextual factors.
2. ***Further abstraction of intervention components.*** The initial models attempted to depict the specifics of the intervention, however, as this was at such an early stage in the development process, these could only be based on supposition. For example, at the time of data collection, an emergency contraception ordering and delivery system was a planned component of the intervention, however, by the time of final analysis of the data, this was deprioritised in favour of the OCP service. Therefore, the final model considers the fundamental inputs of the intervention that were drawn from the data and would be integral to the service, irrespective of the specifics such as contraceptive method type and timing of pregnancy risk.
3. ***Breakdown of final outcomes into proximal, distal and ultimate outcomes.*** The causal pathways were initially unclear and complex. The value of the model as a tool for the evaluation was emphasised through the analysis process, therefore the interim outcomes needed to be identified to shape the empirical studies that were to follow.

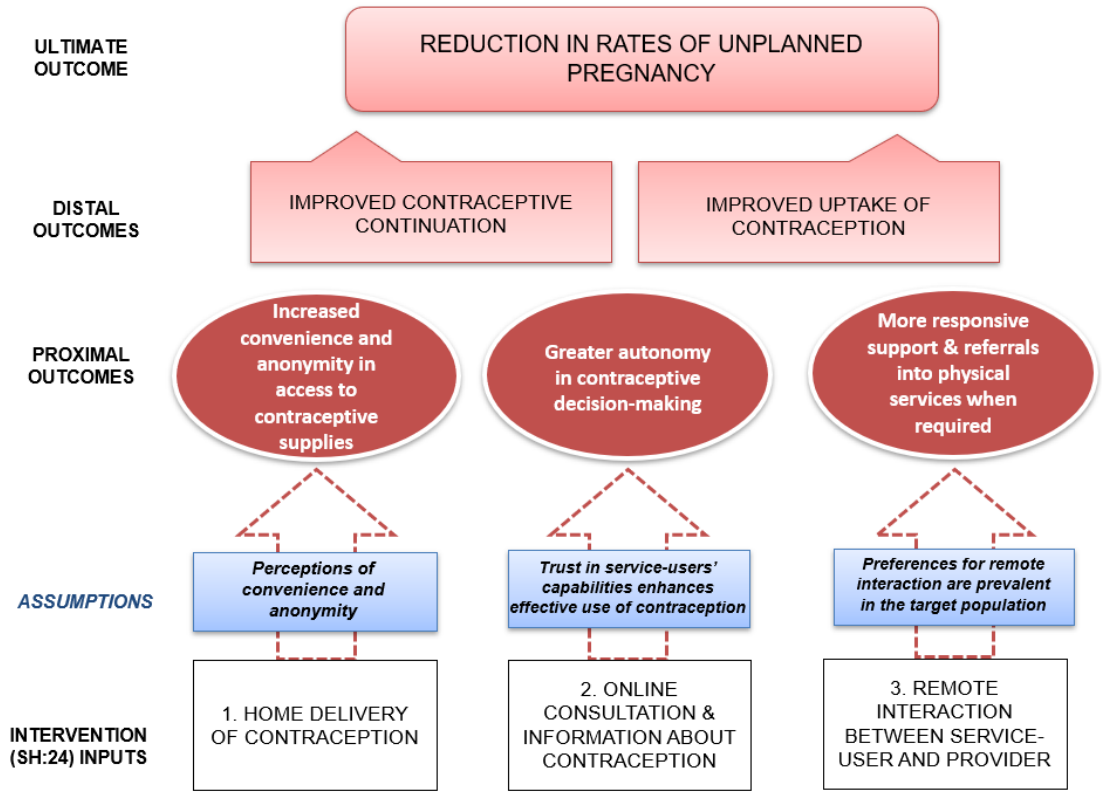


Figure 4-2 Theory of Change Conceptual Model

4.6.2 Assumptions

Stakeholders predicted that the costs and benefits of the intervention would be variable between users and identified unintended outcomes including restricted access to online contraception for those who could not receive packages at home and restricted choice of method to those that did not require an intervention. The positive processes of change from inputs to outcomes illustrated in Figure 4-2, were underpinned by assumptions which are critically analysed below.

Assumption One: Online contraception increases access according to perceptions of convenience and anonymity

Online contraceptive services were not felt to be equally convenient for all potential users. Stakeholders described their value for those who might be time poor, already knowledgeable, comfortable with technology and valuing rapid access.

> "Increasing access to people who are switched on, they know what they want…are very knowledgeable, don't like waiting, don't like queuing, don't like coming to a walk-in service because they have to wait 2 hours..." (*Senior Contraceptive Nurse*)

These priorities were layered onto existing relationship with services and type of contraceptive used. For example, online services may offer no advantage of convenience for regular users of existing services who are established on their method and value the routine and familiarity of

family doctor visits, but may be highly convenient to those who are unable to get home from work in time for an appointment and who require supplies every three months.

> "Quite often now in a lot of services, people are getting a year's worth of contraception anyway…It's not massively onerous for people to pop in once a year." (*Senior Contraceptive Nurse*)

Closely related to the concept of convenience was the assumption that online services would offer greater anonymity to contraceptive users than physical attendance at face-to-face services. This new route to access was also assumed to provide choice to service-users who feel alienated from face-to-face access. This was usually talked about in relation to young people for whom physical attendance could be perceived as especially daunting or stigmatising.

> "We know there are still issues about people who wouldn't want to see their GP, particularly younger people, or people whose parents are still registered at the same practice." (*Public Health Executive*)

However, this perception of anonymity was predicted to be shaped by individual circumstances. Some service-users may find that use of face-to-face care could offer reduced visibility to social networks if services distant from home or work are used. Online services remove the need to travel but packages delivered home or communications on phones or personal computers can reveal service use. As with convenience, the importance of different types of anonymity were predicted to vary with time and person.

> "I'm thinking about people's whose time is being controlled it's probably not going to help them get effective contraception because they probably won't be able to go and pick it up and if their time is being controlled then possibly their post is also monitored. (*Public Health Registrar and Researcher of Online Health*)

The perceived trustworthiness of the service was considered important to foster the sense that any personal data inputted online would be as confidential as data provided in face to face services. This trust was predicted to come from experience of online services outside health care. This experience and familiarity were also associated with being in a younger demographic.

> "It's experience. How many times have I used my card online and how many times have I been defrauded? For me personally, the answer is never. So that gives me the confidence to continue doing it... So, when someone says, 'how would you feel about putting in your details and ordering the pill?' I think, 'well yeah, great, I do that all the time'." (*Developer of Online SRH Services for Target Population*)

> "It is available, it is accessible; it is embedded in new technology, which is very much the way that younger generations do operate these days. They access most services online." *(Healthcare commissioner)*

<u>Assumption Two: Trust in service-users' capabilities enhances autonomy in contraceptive decision-making and leads to more effective use of contraception</u>

The intervention input of online contraceptive information was seen as integral to enhancing service-users' autonomy and ability to make effective contraceptive decisions. It was also posited as filling a gap in existing provision.

> "I've been on methods of contraception where I haven't been happy and I wanted to change and then getting that advice, that knowing what's out there, it hasn't been particularly easy to know what's out there and I've had to be quite motivated to go and find the method of

> contraception that's actually fitted me, or suited me best and it hasn't been immediately apparent from face-to-face services… so I had to do my own research." *(Public health registrar*)

> "I think that the opportunities for people to access more information and to be able to make informed choices has got to be very positive." (*Senior Outreach Worker)*

The online consultation process would require service-users completing their own medical history and biometric measurements. Stakeholders pointed to the heightened level of trust that would have to be placed in the skills of online service-users to fulfil these requirements accurately. It was recognised that the online service required a shift from traditional patterns of provider-led contraceptive provision to one that acknowledges the autonomy of the service-user and requires the development of trusting relationships.

> "…sort of letting people be a bit more in charge of their own contraception. The idea that we trust you to put in your blood pressure check, we don't need to check it ourselves, you're an adult, you understand the risks." (*Public Health Registrar and Researcher of Online Health)*

Yet they also identified the risks of transferring more responsibility to service-users and questioned the ability or willingness of some users to effectively and safely take this on. Some stakeholders focused on the intervention inputs required to provide information in such a way that these risks would be minimised.

> "…[They] might not have good reading skills, they go on the website and then they misinterpret it. They're still at risk." (*Service-User of local SRH services and potential service-user of SH:24)*

> "…there has to be advice and guidance and information and preventative stuff and all that, but it has to be done in a really accessible, readable way." (*Service-user of local SRH services and potential service-user of SH:24)*

There were concerns about the impact of online services on vulnerable users who might have additional needs that autonomous access may not meet. The following quotation uses the adjective "young" for this imagined, vulnerable service-user, highlighting a tension in the data between the assumption that young people would prefer online access whilst also emphasising that many require the holistic, supportive care expected from face-to-face providers.

> "There is the possibility, and you can't legislate for this, but a vulnerable young person, if they would have a face-to-face in a clinic, safeguarding aspects about their lives might emerge. Well in fact we know they frequently do. If they are accessing a remote service, that safeguarding element might be lost." (*Senior Manager of SRH services for target population*)

It was also recognised that an online provider could potentially offer supportive care through the availability of remote communication with the clinical team.

<u>Assumption Three: Preferences for remote interaction are prevalent in the target population</u>

Stakeholders predicted increasing public expectations of rapid support for questions arising after the clinical consultation which were being cultivated through the faster, more responsive and more accessible help increasingly available through online retail and banking. This immediate, responsive access was contrasted with the challenges of accessing advice in clinic settings.

> "I think a lot of people want immediate access and they want to do it in their own way…from a computer at home or from their smart phone. They expect to be able to get that advice and they then expect to be able to make quite rapid decisions about what they do next." (*Public Health Executive)*

> "There's also that immediacy of speaking to somebody, whereas people know this clinic; you may have to sit around for three, four, hours to speak to somebody." (*Client Support Worker)*

Remote interaction was also depicted as a low risk stepping stone for first time use of clinical services. For those in the target population feeling apprehensive about physical attendance, remote support could represent the first step towards engagement with clinical care.

> "It would give the option to either pick up a phone and have that first conversation to admit to whatever the issue is. Maybe that's one way we can then say, "Why don't you come in, and we can go through what needs to happen next, or talk to you, listen, and we can try and help as much as we can, give you options." (*Client Support Worker)*

Online services may increase service-user choice of service and time, place and mode of access but may limit choice of contraceptive method to those that can be posted home – excluding those that require a clinical procedure.

> "…the big thing that's missing from this service, is long- acting reversible contraception. And potentially that's, you know, not giving users the complete range of contraception that's available." (*Public Health Registrar)*

Stakeholders felt that this risk was moderated when online services were considered to be integrated within wider systems of contraceptive care, for example, through the online providers referring service-users into face-to-face providers should they express interest or suitability for LARC. They felt that the intervention's capacity for success in achieving positive health outcomes included facilitating access across different types of services according to need.

> "I would hope that it is something about the whole thing hanging together. About it not being, you know, a defined and beautiful project, but something that actually does make the other bits of the system sort of join in or change… that it makes sense as a whole. That SH:24 will have an impact on mainstream services really." (*Public Health Executive)*

4.7 Discussion

4.7.1 Key Findings

This analysis describes stakeholders' perspectives regarding the inputs and proximal outputs through which an online contraceptive service could improve contraceptive continuation and uptake and decrease unplanned pregnancy. It is predicted that the online service could offer convenience, anonymity, autonomous access, responsive support and expanded choice of service but that positive processes of change are based on assumptions around the characteristics and perceptions of those most likely to use and benefit from key intervention inputs. The narrative explores some of the potential risks of the intervention, stressing the importance of meeting the varied needs of a diverse population and the value of maintaining existing contraceptive choices through integrating the intervention within the wider landscape of provision.

4.7.2 Methodological Considerations

Strengths

This qualitative study has surfaced and interrogated the implicit assumptions underpinning the processes of change predicted to ensue following the introduction of SH:24's online

contraception service into the target population of Lambeth and Southwark. This has been essential in the absence of a precedent in the literature for an intervention of this complexity, scale and within a context of free contraceptive provision and disproportionately poor reproductive health outcomes. The narrative accompanying the model reveals some of the tensions and nuances within the assumptions, with stakeholders recognising that the way in which the target population perceive and respond to the various inputs will vary according to individual characteristics and the timing and circumstances of use.

The use of a theory of change approach based on the literature on theory-driven evaluations has facilitated the development of a conceptual model that is reflective and realistic as recommended for evaluations of complex interventions. The use of multiple data sources has allowed the model and narrative to encapsulate a range of stakeholder viewpoints both within the internal development team and beyond, including those with intimate knowledge and experience of contraceptive provision in these areas (293). The final model is a result of in-depth, multi-stage analysis of the data and incremental refinement. The parsimony of the final model is conducive to the iterative and responsive design approach adopted by the SH:24 intervention developers, whereby specific inputs can be subject to rapid alterations. Therefore, the final model considers the fundamental inputs of the intervention that were drawn from the data and would be integral to the service, irrespective of the specifics such as contraceptive method type and timing of pregnancy risk.

Limitations

The context-specific expertise and experiences of the sample has allowed exploration of the processes of change that could be initiated by this innovative and complex intervention. However, a central limitation is that most of the sample had experiences that were entrenched in the pre-intervention context of face-to-face contraceptive services so may have been inclined towards a more apprehensive outlook on the changes that could be imposed by online services. Conversely, participants may have presented a more positive attitude toward online services if they perceived the interviewers to be representatives of the intervention. As much as possible this was counteracted by interviewers encouraging participants to think through both positive and negative consequences of the intervention, as can be seen in the interview guide (Table 4-3).

Essential to the ToC approach is to generate an evaluation that seeks both internal and external validity for its empirical findings. Achieving external validity is necessary to explain the interplay between the context, the intervention and its effects (283, 291). It has been emphasised that the majority of the sample had very localised experience, knowledge and expertise. This was a strength in terms of understanding the specifics of this target population, particularly in terms of the existing landscape of contraceptive provision. However, the conceptual model and narrative are limited in terms of broader contextual factors, in particular health inequalities and societal hierarchies that operate beyond the local level and require more abstract, theoretical analysis.

4.7.3 Findings in Relation to Other Studies

In terms of the wider literature, there exists support for some of the positive assumptions contained in the model. For example, some recent studies support the potential for remote messaging interventions to improve contraceptive knowledge (43) and effective use of contraception (34, 35, 44, 300). One randomised controlled trial (RCT) assessed the effect of daily text messages on OCP continuation among new OCP users from an urban family planning health centre in the United States (44). At 6 months, effective OCP use was higher in the intervention than the control arm (64% (223/346) (versus) 54% (182/337), respectively; p =0.005*).* Research on e-health SRH interventions in Britain has been focused on outcomes related to STIs, including a pilot RCT which reported that a safer sex intervention delivered by text message increased knowledge of and confidence in how to use condoms (33) and studies that indicate young people have preferences for online testing (31, 301) and that testing becomes more accessible when delivered online (193). The dearth of literature on online contraceptive interventions of this complexity and scale and with relevance to a British context, emphasises the importance of articulating a theory of change to drive a theory-based evaluation of online contraception services.

4.7.4 Findings in Relation to Theoretical Framework

In section 4.7.2 it was mentioned that the conceptual model and narrative are limited in terms of broader contextual factors. It is for this reason that the theory of change conceptual model is used in conjunction with the theoretical framework presented in Chapter 3. The narrower focus of the findings in this chapter also provide some specific conditions for the application of the sociological concepts that have been introduced. It was posited in the previous chapter that online contraception is a structural shift in provision that could fundamentally alter the power dynamics involved in the interaction between a service-user and provider in the contraceptive consultation process, giving contraceptive service-users in Lambeth and Southwark greater agency in terms of access to information, but also greater choice in terms of the mode of access to OCPs and the option to communicate with their contraceptive provider using remote modes of communication including text messaging. Many of these concepts are reflected in the themes in the narrative of this study, such as the power and agency that could be cultivated in patients through improved access to information and enhanced choice of provider. The alteration in the patient-provider interaction is exemplified in stakeholders' comments about patients being asked to remotely provide their own biometric measurements including their BP data, emphasising that with increased patient agency comes increased personal responsibility. Providers who are more accustomed to face-to-face provision could view online access as a contestation of their power to facilitate access and use of contraception safely and effectively. In this sense, greater patient agency could also be considered as the transfer of a certain degree of responsibility from provider to patient in ensuring that access and use of contraception is safe and effective.

The Bourdieusian lens is also useful in considering the notion expressed by several stakeholders that the vaguely expressed concept of “younger generations” would predicate preferences for the intervention. Conversely, youth was also expressed as a characteristic that would engender a greater need for face-to-face consultations. Bourdieu was critical of logic that divided society by generations, arguing that age could not transverse class divisions (268, 269). However, he did advocate that there could be generational unity within specific fields (271, 272). This links back to the topic of “Internet habitus” discussed in section 3.4.4 where accumulation of e-health literacy among particular groups, including the young, could lead to socially patterned health outcomes resulting from the proliferation of online services such as SH:24. The role of age as a unifying force in society and the extent to which this is related to the distribution of capital that could enable access to and effective use of an online contraceptive service is important to consider in the context of health inequalities. Young people could be categorised as a high-risk group, but within this simplistic generational division lie further groupings with associations for effective contraceptive practice, including ethnicity, socioeconomic status and education. Age, along with a number of other sociodemographic and relevant background factors, will be measured within the quantitative studies that follow to enable further understanding of how it may impact uptake and effective use of the online service.

4.7.5 Implications

This is an exploratory study that has articulated the theory underpinning the intervention which not only has implications for this evaluation but has also contributed to the emerging literature on complex, online, contraception interventions. It has revealed the assumptions that stakeholders have about digital and remote contraceptive provision, both in terms of the expected response from the target population and the expected integration of the intervention into the existing landscape of services. It is recommended that these perceptions are considered both by the designers of the online contraception intervention, but also those designing and commissioning innovative strategies to expand contraceptive healthcare services in other contexts. This study, in addition to the theory of change which focused more on the STI component of the service (195), also demonstrate the value of this approach in driving the development of rigorous evaluations of complex, innovative health interventions.

4.7.6 Directions for Future Research

The ToC study has been hypothesis-generating, indicating several avenues for research, not all of which can be pursued within the confines of this thesis. The model (Figure 4-2) indicates a distal outcome of improved uptake of contraception that could result from the intervention. Further research in this area would require data from participants not already accessing contraception and who are likely to be experiencing unmet need. An RCT design is recommended, such as that employed by Wilson et al. (2018) to test the effectiveness of the online testing and results element of the SH:24 service (193), which exposed participants to promotional information pertaining to either the online service (intervention arm) or existing,

face-to-face services (control arm). This would permit the testing of the hypothesis that online contraception could increase uptake of contraception among a population with unmet need.

Central to the ToC conceptual framework and narrative presented in this chapter has been the surfacing of assumptions that underpin the positive processes of change. The assumptions articulated by stakeholders were centred on the perceived characteristics of service-users who would prefer and benefit from remote rather than face-to-face access to contraception. This has driven the design of the descriptive study in Chapter 5 which describes the sociodemographic characteristics and patterns of use for those accessing the service in its first period of availability according to the routine data collected by the online service.

A critical focus of the qualitative results was the extent to which the intervention would be embedded within existing provision, thus the cohort study detailed in Chapters 6 and 7 will observe contraceptive service use across both existing, face-to-face providers and the online contraception service with comparison of outcomes between those using the online platform for their OCPs compared to those using community clinics and general practice. This tests the prediction that online contraception can improve contraceptive continuation, which is a distal outcome in the ToC model. Specifically, it tests the hypothesis that significantly more OCP users accessing SH:24 for their first 3 months' supply of pills will obtain a second pack of OCPs when compared to new OCP users accessing face-to-face services. It is not possible to power this study for the detection of differences between the online and other services group for the outcome of unplanned pregnancy as the rarity of this event would require a large sample size, which is beyond the resource and time constraints of this thesis. Nonetheless, Chapter 6 will report the occurrence of pregnancy and if there are differences in this outcome between the online and other services group.

4.8 Summary of Chapter 4

- The conceptual model and narrative presented in this chapter uses a ToC approach based on the TDE literature.
- In order to encompass a range of stakeholder viewpoints, three data sources have been analysed: the original programme funding application; transcripts of interviews for a related theory of change study and seven supplementary in-depth interviews using a three-stage, inductive, thematic analysis using a framework approach.
- The final theory of change conceptual model depicts the positive processes of change that stakeholders predicted could be initiated through the introduction of the intervention. It suggests that the ultimate outcome of a reduction in rates of unplanned pregnancy could be achieved by improving contraceptive continuation and uptake through three proximal outcomes: 1) increased convenience and anonymity in access to contraceptive supplies; 2) greater autonomy in contraceptive decision-making via online information and the online consultation process; and 3) access to more responsive provider-support to maintain choice across the landscape of providers.

- The assumptions that underpin the positive processes of change have been explored through the accompanying narrative and reveal the pertinent questions for the evaluation. Namely, determining the characteristics of service-users and whether the intervention will facilitate improved continuation of contraception when compared to those using community clinics and general practice.

5 A Description of the Service-users of Online Contraception

5.1 Chapter Overview

The theory of change conceptual model depicts the positive processes of change that stakeholders predicted could be initiated through the introduction of the intervention. Stakeholder assumptions were centred on predictions about the characteristics of the target population that were likely to encourage or inhibit effective use of the online service. This chapter seeks to test these by describing the characteristics of those who used the online contraception service during its first 15 months of availability using SH:24's routinely collected data. Also identified are the factors associated with repeat use of the online contraception service during this period.

5.2 Background and Rationale

In Chapter 4, assumptions generated through the qualitative study centred on which members of the target population would be drawn to the online service and what characteristics might lead to them experiencing positive or negative contraceptive outcomes as a result. At the time of data collection for the qualitative study (2013 – 2015), the precise components of the intervention had not been established and the intervention was yet to be released in Lambeth and Southwark.

During the period 2015 to 2017, the intervention developers designed and tested the online contraception component of the SH:24 service. It launched in January 2017 and was available to Lambeth and Southwark residents as online contraceptive information and clinical assessment with combined and progestogen only OCPs ordered online and sent home, free of charge and all supported via text or phone calls between the service-user and provider. It was the first of its kind to be freely available as an NHS-commissioned service and represented a fundamental shift in contraceptive service provision which had previously only been available via community clinics, general practice and private retailers. The process of ordering OCPs from SH:24's contraception service translated the face-to-face consultation a patient would experience at a general practice or community clinic to a remote, online platform. The SH:24 service-user could view information about all methods of contraception and then complete an online clinical assessment should they wish to order OCPs directly to their home address. The service had similarities to a face-to-face clinical experience, as well as having parallels to the ordering process of a private online retailer. In the absence of an accepted body of literature for this innovative intervention, the terminology employed in this chapter has been chosen to reflect aspects of the process relevant for this quantitative study and is explained in Figure 5-1.

Terminology

Service-user: An individual who has filled in an online consultation or assessment to access a supply of oral contraceptive pills (OCPs) from the intervention, SH:24's online contraception service. Service-users have inputted enough information for their order to be confirmed, logged and recorded in the routinely collected dataset.

Complete order: Within SH:24's routinely collected dataset, a date and time was recorded for all OCP orders which had been dispatched by the service for postal delivery to the service-user's home address.

Incomplete order: This denotes that a confirmed order for OCPs was not dispatched to the service-user's home address. This was determined by the absence of a dispatch date within the routinely collected dataset. The reasons for incomplete orders included the service-user having listed a medical contraindication to their OCP of choice during the consultation process or that the service-user had informed the provider not to dispatch the OCPs after receiving confirmation of the order.

Repeat orders: Two or more complete OCP orders made by the same service-user.

Non-repeat orders: One complete OCP order made by one service-user. Service-users with only one complete order were excluded for the purposes of analysis if the date of access indicated that their index supply would still be in use.

Figure 5-1 Study Terminology

An initial step towards testing the assumptions surfaced within the theory of change model was to determine the characteristics of the users of the intervention during its first 15 months of availability. The exploratory study in this chapter is a quantitative description and analysis of the online intervention's routinely collected data to determine available service-user characteristics and contraceptive activity.

5.3 Aims and Objectives

The primary aim of this study is to describe the characteristics of service-users of online contraception in its first period of availability, 10th January 2017 to 25th April 2018, in the boroughs of Lambeth and Southwark. The study fulfils the following objectives.

To describe the characteristics of the service-users of SH:24's online contraception service from January 2017 to March 2018 using the data routinely collected by SH:24.

- To describe the characteristics of the service-users of SH:24's online contraception service from January 2017 to March 2018 using the data routinely collected by SH:24.
- To describe overall patterns of service-use during this time including:
    - The total number of OCP supplies ordered and dispatched to the home address of the service-user, referred to as a "complete order".
    - The total number of orders of OCPs that were initiated but were abandoned or prevented from being completed to the point of dispatch, referred to as an "incomplete order".
    - The proportion of service-users with at least one complete order.
    - The proportion of service-users with both complete and incomplete orders.
    - The proportion of service-users with two or more complete orders, referred to as those with "repeat orders".

- To describe patterns of service-use for service-users who made repeat orders according to:
    - The proportion of individual service-users by number of complete orders.
    - The time interval in days between repeat orders.
    - The proportion of service-users with repeat orders who order their new supplies of OCPs within a time frame necessary for adequate contraceptive coverage.
- To describe the factors associated with repeat OCP ordering from SH:24, comparing those service-users who made repeat orders with those who made one complete order, excluding those for whom an insufficient period of time had elapsed for them to have completed their index supply of OCPs.

5.4 Methods

This study used the routinely collected data from SH:24's first 15 months of availability to residents of Lambeth and Southwark to derive all stated outcomes.

5.4.1 Dataset

The online contraceptive service-provider in Lambeth and Southwark, SH:24, provided the dataset containing information on all contraceptive orders from their launch on 10th January 2017 until 25th April 2018 (the date on which the data was requested). Data was provided in an anonymised form and arranged by order, rather than by service-user. This was an automatically generated database reflecting the online ordering process completed by service-users and the provider's system of recording dates that orders had been initiated and dispatched.

Data was generated for an OCP order in the event that an individual service-user had filled in the necessary details for the online consultation including name, age, postcode, medical history and questions on medical contraindications. Should the service-user have reached the confirmation page, her order would be logged and data for the order recorded. Individuals that did not reach the confirmation page had not completed the ordering process and their data was not recorded as part of the routinely collected dataset. These individuals are not included in this study. Reasons for not reaching the confirmation page included submitting a date of birth that indicated the individual was below the age of 18 years, submitting a postcode that was not within the boroughs of Lambeth or Southwark or abandoning the process before the order could be logged (Howroyd C [Service Development Director] 2018, oral communication, 18th May).

There were two OCPs that service-users could order, either Desogestrel (75 micrograms) - a brand of POP or Levonorgestrel/ Ethinylestradiol (150 micrograms) – a brand of COC. The ordering process for COC entailed some additional questions compared to the POP process due to the added medical contraindications, for example, those ordering COC had to provide their BP. It is a plausible assumption that an inability to provide an accurate BP measure would be a reason for abandonment of the ordering process (Howroyd C [Service Development Director] 2018, oral communication, 18th May). In addition to type of OCP, the service-user could also be offered either a 3 months' or 6 months' supply. Typically, new service-users were

provided with a 3 months' supply and repeat service-users received 6 months', however, this was subject to the clinician's discretion during the ordering process.

After the service-user had reached the confirmation page and the data for the order had been logged, there would be a period of time before the order was dispatched to the service-user's address during which the order could be terminated. If the dataset contained a dispatch date for the order this was considered this to be a "complete order" and if the order did not contain a dispatch date it was assumed that the OCPs were not sent and therefore the order was "incomplete". The reasons for incomplete orders included the service-user having listed a medical contraindication to their OCP of choice during the consultation process or that the service-user had decided against completing the order and had informed the provider not to dispatch the OCPs.

5.4.2 Inclusion in Descriptive Sample

The descriptive results were initially not subject to any inclusion criteria. Data were first described according to OCP orders. The unique identifying variable for each service-user was "customer id" which was a section of the service-user's mobile phone number and appeared more than once if the service-user had made multiple OCP orders during the data collection period. To account for the possibility that more than one individual could have feasibly ordered from the same phone number, the customer id variable was merged with the date of birth listed for each order to generate a new, variable called "user id". This enabled the description of individual service-users according to their sociodemographic characteristics and patterns of service-use.

In order to fulfil the objective to describe patterns of service-use for service-users who made repeat orders, some exclusion criteria had to be implemented in two stages. Firstly, those service-users with only incomplete orders (initiated an OCP order that was abandoned or prevented from being completed to the point of dispatch) were excluded. This enabled the description of patterns of service-use for those with complete orders only. Following this, service-users with only one complete order were also excluded so that time intervals between repeat orders could be described. These points of exclusion are shown in the study flow diagram (Figure 5-2).

5.4.3 Inclusion in Analytic Sample

In order to analyse differences in sociodemographic data between service-users who had one complete order to those with repeat orders, the analytic sample was restricted to remove service-users whose index OCP order had not yet expired. This was done according to the service-users' date of attendance, so they were subject to exclusion if they created their first order of a 3 months' supply of OCPs after 30th January 2018 or 7th November 2018 if the supply

was for 6 months. In addition, service-users were excluded from analysis if they had no complete orders.

5.4.4 Descriptive Variables

The primary aim of the study was to describe service-users. This was conducted using SH:24's routinely collected data on sociodemographic characteristics. These variables were generated through the online ordering process completed by service-users. Service-users were described according to the sociodemographic variables generated at their index order. Therefore, this study does not account for the time-varying nature of the age variable or any other changes to variables that may have occurred after the index order. Further variables pertaining to the ordering process were used to fulfil the objectives to describe overall patterns of service-use.

Age (years): The dataset contained the date of birth and the date and time that the order was created for each service-user. Date information was extracted to create a variable of the date of attendance for each service-user. The date of birth and date of attendance was used to generate the age of the service-users.

Ethnic group: All service-users submitted their ethnicity during the ordering process. To maximise the potential for power during the analysis stage, ethnicity categories were collapsed into Office for National Statistics (ONS) top line categories; i.e. white, black, Asian, mixed ethnicity or other (302).

Index of Multiple Deprivation (IMD): The dataset contained a postcode variable for each service-user. The postcode lookup tool from the Ministry of Housing Communities & Local Government website was used to acquire deprivation data (186). The relevant data was the IMD decile which was downloaded according to the variable, user id, and then merged back onto the original dataset. The decile categories were collapsed into quintiles to increase the likelihood of adequate power at the analysis stage.

Type of OCP: This was a binary variable with service-users having the option to order either a particular brand of COC or POP. Type of OCP was reported for all service-users using data from the index order.

Completion of order: Service-users were considered to have a complete order if the dataset contained both a date on which the order was created and a date on which the order was dispatched. OCP orders with only a date on which the order was created and no dispatch date were considered to be incomplete orders. From this, a binary variable was generated to mark whether each order was complete or incomplete. The maximum number of orders per individual was 5, therefore the dataset set contained variables for 5 orders per individual. Another variable was generated to be the sum of these variables, called "order total", therefore each individual service-user had a number from 0 (no complete orders) to 5 (5 complete orders). A further

categorical variable was generated from these dates of access to establish whether service users had no complete orders, one complete order, multiple complete and incomplete orders or multiple complete orders.

Time interval between repeat successful orders (days): The time interval between subsequent complete orders was determined as a continuous variable (days). This was through sorting the data by individual and by their various dates of attendance, enabling the time intervals between consecutive complete orders to be calculated.

Adequate contraceptive coverage: The time interval data in addition to data on whether the supply was for 3 or 6 months were used to generate a binary variable to determine whether the subsequent order was made within a time frame adequate to provide contraceptive coverage for the transition between OCP packets. Service-users whose previous order was a 3 months' supply were considered to have adequate coverage if their subsequent attendance date was less than 85 days after the previous one, whilst for a 6 months' supply the subsequent attendance date had to be less than 169 days.

5.4.5 Analysis

1. Descriptive data for service users of SH:24's online contraception service were determined using the service's routinely collected data from January 2017 to April 2018 including:
    a. Age (years)
    b. Ethnic group
    c. IMD quintile
    d. % service-users ordering either COC or POP for their index order
    e. % service-users with a complete index order.
2. Descriptive data for patterns of service-use were determined including:
    a. % service-users with only an incomplete order
    b. % service-users with one complete order
    c. % service-users with both complete and incomplete orders
    d. % service-users with multiple complete orders
    e. Time interval between service-users' subsequent complete orders (days)
    f. % service-users within each time interval experiencing adequate contraceptive coverage.

3. Repeat and non-repeat users of the online service were described.
4. Bivariate analysis using chi-squared tests was conducted to test associations between age group, ethnic group and IMD quintile and the outcome of repeat orders of OCPs from the online service.
5. Crude logistic regression was then performed to examine the strength of association between age group, ethnic group and IMD quintile and the outcome of repeat orders of OCPs from the online service.
6. A further exploratory logistic multivariable analysis was conducted to examine the strength of association in the presence of all available sociodemographic variables, i.e. age group, ethnic group and IMD quintile and the outcome of repeat orders of OCPs from the online service. Initially, the analysis plan was to only include covariates that were significant at the bivariate level with a p value of <0.05, however, only one categorical covariate was significant, so it was decided to include even those with a p value of >0.05 into the model, based on a priori knowledge, providing a conservative test of the strength of the association to the outcome of repeat orders in the presence of the other sociodemographic variables.

All analyses were conducted with the use of STATA V.14.1 (StataCorp).

5.4.6 Ethical Considerations

Ethical approval for this research was granted by The Proportionate Review Sub-Committee of the National Research Ethics Service (NRES) Committees – North of Scotland (Ref 15/NS/0031) (Appendix T). All data was routinely collected and anonymised and as such, no identifiable data was apparent within this study.

5.5 Results

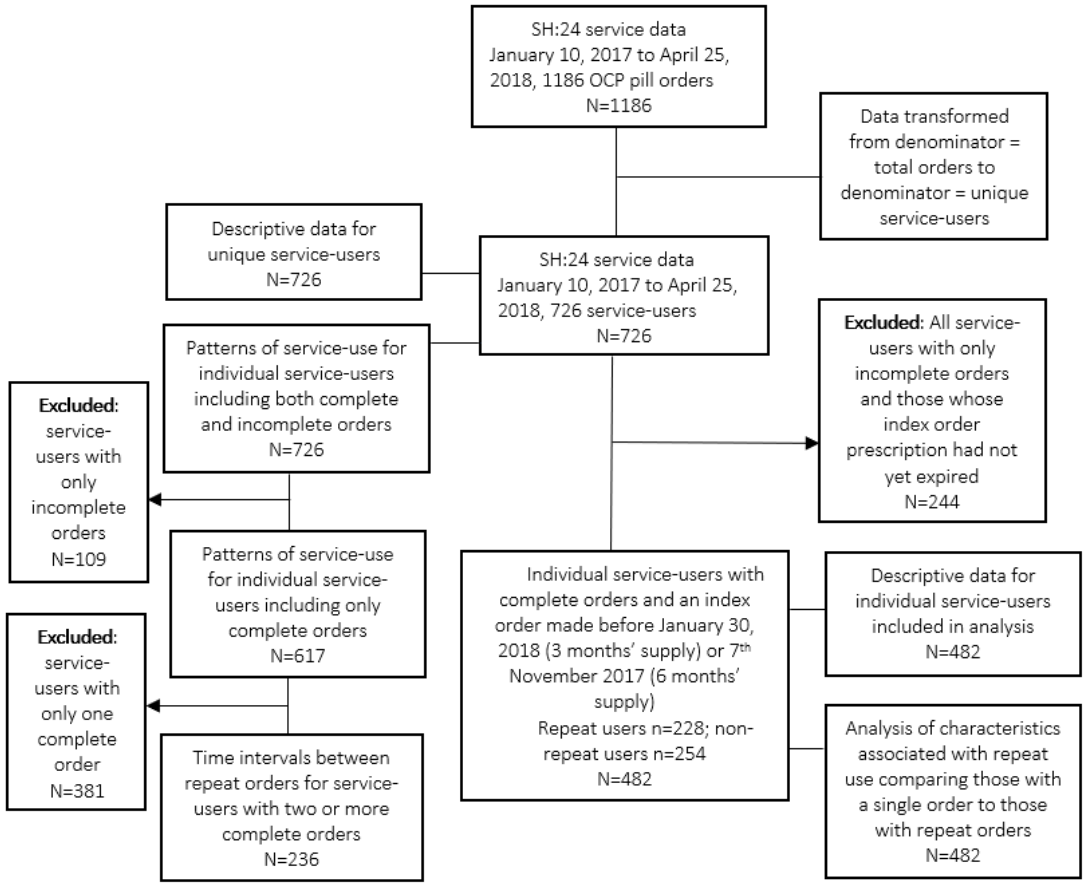


Figure 5-2 Study Flow Diagram
Oral contraceptive pill, OCP

5.5.1 Description of all Orders from the Online Service

The online contraceptive service freely available to residents of Lambeth and Southwark, was accessed a total of 1186 times from its launch on 10th January 2017 to 25th April 2018. Among these 1186 attempts to order, 207 (17.5%) were incomplete and 979 (82.6%) were complete; 558 (47.1%) were POP orders and 628 (53.0%) were COC orders. Out of the POP orders, 84 (15.1%) were incomplete, whereas 123 (19.6%) of COC orders were incomplete. Data was not available on the number of months prescribed for 103 attempted orders. For the 1083 orders for which this information was available, 769 (71.0%) were for a 3 months' supply of OCPs and 314 (29.0%) were for a 6 months' supply.

5.5.2 Description of all Service-users of Online Contraception

The total number of unique service-users accessing the intervention was 726. Service-users were aged between 16 and 53 years (median=25; IQR=17-50). The majority of these service-users were aged between 20 and 29 years with 272 (37.5%) aged between 20 – 24 years and 254 (35.0%) aged between 25 – 29 years (Table 5-1). In terms of ethnic group, here reported with the ONS categories collapsed into the top line ethnic groups, the majority of individual service-users, 427 (58.8%) were in the White ethnic group. Most service-users were residents of areas classified as being in the 1st and 2nd most deprived quintiles, 283 (39.1%) and 292 (40.4%) respectively.

Table 5-1 Descriptive Data of Service-users Accessing Online Contraception between 10th January 2017 and 25th April 2018 (n=726) (pertains to index orders only)

	%	95% CI	N
Age group (years)			
16 - 19	9.0	(7.0 – 11.3)	65
20 – 24	37.5	(33.9 – 41.1)	272
25 – 29	35.0	(31.5 – 38.6)	254
30 – 34	10.5	(8.3 – 12.9)	76
35 – 39	5.7	(4.1 - 7.6)	41
40 +	2.5	(1.5 – 3.9)	18
Ethnic group			
White	58.8	(55.1 – 62.4)	427
Black	17.6	(15.0 – 21.2)	128
Asian	8.5	(6.6 – 10.8)	62
Mixed	10.5	(8.3 – 12.9)	76
Other	4.6	(3.2 – 6.3)	33
IMD†			
1st quintile (most deprived)	39.1	(35.6 – 42.8)	283
2nd quintile	40.4	(36.8 – 44.1)	292
3rd quintile	16.7	(14.1 – 19.7)	121
4th quintile	3.5	(2.3 – 5.1)	25
5th quintile (least deprived)	0.3	(0.0 – 1.0)	2
Index order			
POP	46.6	(43.0 – 50.3)	338
COC	53.4	(49.7- 57.1)	388
Index order complete			
Yes	81.3	(78.2 – 84.0)	590
No	18.7	(16.0 – 21.8)	136

Confidence interval, CI; Index of Multiple Deprivation, IMD; progesterone only pill, POP; combined oral contraceptive pill, COC

†Missing data for 3 observations for IMD

5.5.3 Patterns of Service-use from all those Accessing Online Contraception

There were two types of orders: those that were completed successfully and those that were not completed. Out of the 726 unique individuals accessing the service, 109 (15.0%) did not successfully complete their order, i.e. their delivery of OCPs was not dispatched on the one occasion that they accessed the service (Table 5-2). Most service-users did complete at least one order and these were categorised according to whether they had one complete order only, which was the majority at 346 (47.7%), whether they had multiple orders both incomplete and complete (9.9%) or multiple complete orders (27.4%). Of the 617 service-users with at least one complete order, 381 (61.8%) had one complete order, 140 (22.7%) had two complete orders, and 67 (10.9%) had three complete orders, 28 (4.5%) had four complete orders and just 1 (0.2%) had five complete orders (Table 5-3).

Table 5-2 Patterns of Use for Service-users of Online Contraception between 10th January and 25th April 2018 (n=726)

	%	95% CI	N
Types of access			
Incomplete orders only	15.0	(12.5 – 17.8)	109
One complete order	47.7	(44.0 – 51.3)	346
Multiple orders: complete and incomplete	9.9	(7.8 – 12.3)	72
Multiple orders: complete only	27.4	(24.2 – 30.8)	199

Confidence interval, CI

Table 5-3 Proportion of Service-users of Online Contraception by Number of Complete Orders Made between 10th January 2017 and 25th April 2018, Among those with at Least One Complete Order (n=617)

	%	95% CI	N
Number of complete orders			
1	61.8	(57.6 – 65.6)	381
2	22.7	(19.4 – 26.2)	140
3	10.9	(8.5 – 13.6)	67
4	4.5	(3.0 – 6.5)	28
5	0.2	(0.0 – 0.9)	1

Confidence interval, CI

5.5.4 Intervals between repeat OCP Orders for Individual Service-users

The majority of service-users with a minimum of 2 complete orders had a time interval between their dates of attendance to the online contraceptive service that was adequate to provide contraceptive coverage, 143 (60.6%) (Table 5-4). The proportion that had adequate coverage increased as the number of minimum complete orders increased, however the number of service-users reduced from 236 to only 1 with 5 complete orders. This can also be seen in the decrease in mean number of days for each interval (Table 5-5). Fewer service-users with repeat orders obtained a prescription for a 6 months' supply (n=82) than a 3 months' supply (n=280). Those service-users with a 6 months' supply had mean interval lengths of less than 169 days.

Table 5-4 Proportion of Repeat Oral Contraceptive Pill Orders Completed within a Time Frame Adequate to Provide Contraceptive Coverage for Service-users of Online Contraception between 10th January and 25th April 2018 (n=236)

	%	95% CI	N
Minimum of 2 complete orders			
Adequate coverage during interval between 1st and 2nd order	60.6	(54.1 – 66.9)	236
Minimum of 3 complete orders			
Adequate coverage during interval between 2nd and 3rd order	72.9	(62.9 – 81.5)	96
Minimum of 4 complete orders			
Adequate coverage during interval between 3rd and 4th order	96.6	(82.2 – 99.9)	29
Minimum of 5 complete orders			
Adequate coverage during interval between 4th and 5th order	100.0	(2.5 – 100.0*)	1

*one-sided, 97.5% confidence interval
Confidence interval, CI

Table 5-5 Mean Time Interval (days) between Repeat Oral Contraceptive Pill Orders for Service-users of Online Contraception between 10th January and 25th April 2018 According to Length of Supply (n=236)

(126 individuals with >2 complete orders included in observations for interval between 1st and 2nd order and then again in each subsequent interval according to number of complete orders)

	3 months' supply (n=280)		6 months' supply (n=82)		
	Mean (days)	SD	Mean (days)	SD	N
Minimum of 2 complete orders					
Interval between 1st and 2nd order	99	52.84	98	37.48	236
Minimum of 3 complete orders					
Interval between 2nd and 3rd order	92	33.87	109	48.85	96
Minimum of 4 complete orders					
Interval between 3rd and 4th order	76	9.83	108	40.35	29
Minimum of 5 complete orders					
Interval between 4th and 5th order	0	-	141	-	1

Standard deviation, SD

5.5.5 Comparing Service-users with Repeat and Non-repeat Orders

In the analysis of the online OCP service-users, of the 726 unique service-users from 10th January 2017 to 25th April 2018, 482 service-users had at least one complete order and an attendance date for their index order that would give them sufficient time to order their subsequent supply. Descriptive data for these service-users in presented in Table 5-6. Out of these 482 service-users, 254 (52.7%) completed one order and 228 (47.3%) completed two or more orders.

Table 5-6 Descriptive Data of Service-users Accessing Online Contraception between 10th January 2017 and 25th April 2018 Remaining in Analytic Sample (n=482)

	%	95% CI	N
Age group (years)			
16 - 19	6.2	(4.2 – 8.8)	30
20 – 24	44.6	(34.0 – 42.9)	185
25 – 29	37.3	(33.0 – 41.8)	180
30 – 34	10.8	(8.2 – 13.9)	52
35 – 39	5.2	(3.4 – 7.6)	25
40 +	2.1	(1.0 – 3.8)	10
Ethnic group			
White	60.2	(55.6 – 64.6)	290
Black	16.0	(12.8 – 19.6)	77
Asian	8.9	(6.5 – 11.8)	43
Mixed	11.2	(8.5 – 14.4)	54
Other	3.7	(2.2 – 5.8)	18
IMD†			
1st quintile (most deprived)	35.2	(30.9 – 39.7)	169
2nd quintile	42.5	(38.0 – 47.1)	204
3rd quintile	19.2	(15.9 – 23.3)	92
4th quintile	2.9	(1.6 – 4.9)	14
5th quintile (least deprived)	0.2	(0.0 – 1.2)	1
Type of OCP at index order			
POP	48.8	(44.2 – 53.3)	235
COC	51.2	(46.7 – 55.8)	247
Index order complete			
Yes	95.0	(92.7 – 96.8)	458
No	5.0	(3.2 – 7.3)	24

Confidence interval, CI; Index of Multiple Deprivation, IMD; progesterone only pill, POP; combined oral contraceptive pill, COC

† Missing data for 2 observations for IMD

Table 5-7 presents the proportion of service-users who made repeat orders by socio-demographic characteristics. Ethnic group was the only covariate to have a statistically significant association with the outcome of having repeat orders at the bivariate level (p=0.001). Table 5-8 shows that in multivariable analysis adjusting for age group, ethnic group and IMD quintile, ethnic group retained its statistically significant association with repeat orders. Compared with service-users reported as being of white ethnic group, those of black ethnic group were significantly less likely to make repeat orders (adjOR 0.52, 95% CI 0.31 to 0.89; p=0.016). In addition, compared with service-users reported as being of white ethnic group, those of Asian ethnic group were less likely to make repeat orders (adjOR 0.39, 95% CI 0.20 to 0.77; p=0.007), as were service-users in the mixed group (adjOR 0.37, 95% CI 0.20 to 0.70; p=0.002).

Table 5-7 Sociodemographic Characteristics of Service-users of Online Contraception between 10th January 2017 and 25th April 2018 (n=482) Comparing those with a Single Complete Order to those with Repeat Orders

	Service-users with non-repeat order (n=254)		Service-users with repeat orders (n=228)			
	%	95% CI	%	95% CI	N	p value (X^2)
Age group (years)						
16 - 19	53.3	(34.3 – 71.7)	46.7	(28.3 – 66.0)	30	0.972
20 – 24	53.0	(45.5 – 60.3)	47.0	(39.7 – 54.5)	185	
25 – 29	52.2	(44.7 – 59.7)	47.8	(40.3 – 55.3)	180	
30 – 34	55.8	(41.3 – 69.5)	44.2	(30.4 – 58.7)	52	
35 – 39	52.0	(31.3 – 72.2)	48.0	(27.8 – 68.7)	25	
40+	40.0	(12.2 – 73.8)	60.0	(26.2 – 87.8)	10	
Ethnic group						
White	45.2	(39.4 – 51.1)	54.8	(48.9 – 60.7)	290	0.001*
Black	58.4	(46.6 – 69.6)	41.6	(30.4 – 53.6)	77	
Asian	67.4	(51.5 – 80.9)	32.6	(19.1 – 48.5)	43	
Mixed	68.5	(54.5 – 80.5)	31.5	(19.5 – 45.6)	54	
Other	66.7	(41.0 – 86.7)	33.3	(13.3 – 59.0)	18	
IMD†						
1st quintile (most deprived)	48.5	(40.8 – 56.3	51.5	(43.7 – 59.2)	169	0.553
2nd quintile	55.9	(48.8 – 62.8	44.1	(37.2 – 51.2)	204	
3rd quintile	52.2	(41.5 – 62.7	47.8	(37.3 – 58.5)	92	
4th quintile	57.1	(28.9 – 82.3	42.7	(17.7 – 71.1)	14	
5th quintile (least deprived)	100.0	(2.5 – 100.0††	0.00	(0.0 – 97.5††)	1	

Confidence interval, CI; Index of Multiple Deprivation, IMD
* P value significant <0.05
† Missing data for 2 observations for IMD
†† one-sided, 97.5 confidence interval

Table 5-8 Crude and Adjusted Odds Ratios (ORs) for Association between Sociodemographic Characteristics and the Outcome of Repeat Orders of OCPs for Service-users of Online Contraception between 10th January 2017 and 25th April 2018 (n=482)

	Crude OR (95% CI)	p value	Adjusted OR (95% CI)[a]	p value
Age group (years)				
16 - 19	0.99 (0.45 - 2.14)	0.971	0.95 (0.43 - 2.11)	0.901
20 – 24	1 (ref)	-	1 (ref)	-
25 – 29	1.03 (0.68 - 1.55)	0.886	0.95 (0.62 - 1.45)	0.796
30 – 34	0.89 (0.48 - 1.66)	0.721	0.87 (0.46 - 1.65)	0.676
35 – 39	1.04 (0.45 - 2.40)	0.927	1.05 (0.43 - 2.53)	0.915
40+	1.69 (0.46 - 6.19)	0.428	1.78 (0.47 - 6.73)	0.397
Ethnic group				
White	1 (ref)	-	1 (ref)	-
Black	0.59 (0.35 - 0.97)	0.039*	0.52 (0.31 - 0.89)	0.016*
Asian	0.40 (0.20 - 0.78)	0.008*	0.39 (0.20 - 0.77)	0.007*
Mixed	0.38 (0.20 - 0.70)	0.002*	0.37 (0.20 - 0.70)	0.002*
Other	0.41 (0.15 - 1.13)	0.084	0.39 (0.14 - 1.08)	0.069
IMD†				
1st quintile (most deprived)	1 (ref)	-	1 (ref)	-
2nd quintile	0.74 (0.49 – 1.12)	0.157	0.70 (0.45 – 1.07)	0.096
3rd quintile	0.86 (0.52 - 1.44)	0.573	0.79 (0.47 - 1.35)	0.388
4th quintile	0.71 (0.24 – 2.13)	0.537	0.61 (0.19 – 1.93)	0.402
5th quintile (least deprived)	-	-	-	-

Confidence interval, CI; Index of Multiple Deprivation, IMD; odds ratio, OR
* p value significant <0.05
†Missing data for 2 observations for IMD
[a]Adjusted for repeat order from service; age group; ethnic group; IMD quintile

5.6 Discussion

5.6.1 Key Findings

In the first 15 months that the online contraceptive service had been available to residents of Lambeth and Southwark, it was accessed 1186 times by 726 unique individuals. Almost three quarters of the sample were aged between 20 and 29 years and most were of white ethnic group. Nearly 80% were residents of areas in the 1st and 2nd most deprived IMD quintiles. The majority of service-users made at least one complete order and a third made a minimum of two complete orders. Among these service-users with repeat orders, nearly two thirds had a time interval between their 1st and 2nd order that was sufficient to provide contraceptive coverage. The proportion that had adequate coverage increased as the number of minimum complete orders increased, however the number of service-users correspondingly decreased.

In the comparison of service-users with repeat orders compared to those with non-repeat orders, the only covariate that had a statistically significant association with repeat use was ethnic group at the bivariate and multivariable level. Compared with individuals reported as being of white ethnic group, those of black ethnic group were significantly less likely to have repeat orders; an association which remained significant in the presence of other sociodemographic variables (age group and IMD quintile). This was also the case for both the Asian and mixed ethnic groups.

5.6.2 Methodological Considerations

Strengths

This is the first study to describe the users of a free to access, NHS commissioned, online contraception service. This innovative form of contraceptive delivery is a shift from traditionally provided face to face services, namely general practice and community clinics, where the majority of women in England access their OCPs (70). Although the study remains exploratory, it is the first to provide an indication of the types of characteristics that online OCP service-users may possess. Through describing patterns of service-use, it provides some medically relevant outcomes regarding the service-users' experiences of the intervention and the quality of care they received, namely the proportion of service-users who returned to order repeat supplies and who did so without apparent gaps in coverage; gaps which could potentially put them at risk of unplanned pregnancy. Finally, in analysing the associations between service-user characteristics and repeat-use, the study highlights that ethnic group is associated with repeat orders from the service, with black, Asian and mixed ethnic groups having lower odds of repeat use compared to those of white ethnic group.

Limitations

This is an exploratory study using data from the online service during its first 15 months of delivery to this target population; it is therefore confined to the variables which are routinely

collected by the service and to the participants who used the service during this time period. The sample size is relatively small, which is most apparent in the data where patterns of service-use and sociodemographic data have been presented and the numbers occupying subdivided groups are minimal. It also does not facilitate comparisons to service-users from other services or others in the target population.

The small sample size is pertinent in terms of the multivariable analysis where there are very small numbers of service-users of black, mixed and particularly Asian ethnic groups available for sub group analyses (Table 5-8). In addition, the small sample size has prevented analysis according to sub-categories within these ethnic groups. There has been much criticism of epidemiological research that fails to account for differences within ethnic groups, specifically that which does not discern between black Caribbean and black African groups, particularly where the sample has been drawn from an ethnically diverse population (267, 303, 304), which is the case in this study.

This study uses IMD, which is a useful and readily available indicator of deprivation, but one which is limited as it relates only to the area in which the service-user lives, rather than to the status of the individual. This limitation is highly pertinent within this research context as a relatively central location in London with a very socioeconomically mixed population living in close proximity to one another (Figure 2-8).

5.6.3 Findings in Relation to Other Studies

There is a dearth of literature on online contraceptive interventions of this complexity and scale and with relevance to a British context where the majority of contraception users have access to services and prescriptions that are free at the point of access. However, there are studies on e-health SRH interventions focused on outcomes related to STIs, with pertinent findings related to the characteristics of service-users, including studies that indicate young people have preferences for online testing (301) and that testing becomes more accessible overall when delivered online (193). Particularly relevant are studies that have reported the sociodemographic characteristics of the service-users accessing the STI testing component of the same SH:24 platform within the same target population, albeit inclusive of males and others not requiring OCPs. The SH:24 OCP service was not widely promoted during this first period of availability so it is likely that awareness of the service was heightened among those with a contraceptive need who were already accessing the online platform for the STI services. This involves a basic self-sampling kit ordered online and sent to the home by post, which the individual uses in order to return samples for testing to the laboratory in a prepaid envelope. Barnard et al. (2018) found that young people aged between 16 and 20 years and BAME groups were more likely to use clinic services in Lambeth and Southwark for STI testing than SH:24's online STI testing service (194). They also found that among those who obtained a self-sampling kit from the online service, those who were most likely to return the kit for testing were aged over 20 years and were white British. The data presented in this chapter supports the

findings of this study in terms of those who are using the online OCP service. Further research into the differences between online OCP users and OCP users in clinics and general practice is needed to see if the differentials across services are similar to those found for STI testing. In contrast, Wilson et al. (2017) conducted an RCT investigating the same STI service and reported no differences in uptake between sociodemographic groups (193). This may have been related to the nature of the recruitment procedures employed in this study, which took place in the community in areas and venues likely to attract at risk groups, such as further education colleges, universities and dating apps for men who have sex with men (MSM).

Wilson et al. (2017)'s finding suggests that the concentration of service users occupying particular age and ethnicity categories found in this chapter could be a result of lack of awareness of the online OCP service in the target population. The sample of service-users described here represent a unique group of people accessing a service at a relatively early stage of development, prior to its broad promotion, so may not be indicative of preferences for online OCP services associated with age and ethnicity in the wider population. However, the findings in this study relating to ethnicity and particularly those that show ethnic minority groups have accessed and used the service once, but have not used it again, have important public health implications in this ethnically diverse context and should be a priority area for further research and development of the online service.

5.6.4 Findings in Relation to Conceptual Model and Theoretical Framework

This exploratory study is an initial step towards testing the assumptions surfaced within the ToC model (Figure 4-2), using the intervention's routinely collected data to determine the characteristics and contraceptive activity of the initial users of the intervention. The predictions made by stakeholders in the qualitative study contained nuance and complexity, recognising that the intervention was likely to have differential impacts across the population depending on the attributes, timing and circumstances of individuals. The exploratory study in this chapter is restricted in its description of service-users by the variables contained in the routinely collected dataset made available by the online contraception service. Nonetheless, understanding the impact of the intervention according to the age, IMD, ethnic group and the contraceptive activity of the service-users is indicative of the sociodemographic groups in the population who were drawn to the intervention in its initial period of availability and who were likely to use it for repeat ordering of their OCPs.

A key finding of the theory of change qualitative analysis was that stakeholders made frequent associations between youth and preferences for online services. The finding that the majority of the service-users were aged between 20 – 29 years could be corroborative of stakeholders' assumptions that youth would be indicative of preferences for online access, although it was highlighted that participants were not particularly clear on their definition of this concept. The service imposed a restriction on access to those aged 17 years and under, therefore this study does not reveal whether those aged below 18 years in the target population have preferences

for online contraception and so would access it were it to be available. The age restriction is reflective of the stakeholders' concerns about the potential vulnerability of younger service-users who were perceived to be more in need of supportive care and safeguarding considerations than their older counterparts.

These findings can be considered using Bourdieu's concepts of habitus, capital and field. The online service during this initial period of availability, appears to have appealed to particular sociodemographic subgroups of the population, which may be indicative of accumulation of relevant capital in these societal groups predicating awareness and preferences for this form of access to OCPs. Ethnic group may be a forceful driver here, with its association with lower odds of repeat use and the lack of ethnic diversity among those accessing the service. It has been suggested that ethnicity is a form of habitus, with ethnic, and by extension, cultural differences, operating within wider societal power relations which may disadvantage BAME groups in accessing services (266). However, as a mostly descriptive study with limited variables available for analysis, these findings do not reveal understanding of the multiple, interlinked and complex factors involved in contraceptive practice and the role of ethnicity within this. The extent to which the outcomes in this study are associated with capital and how these may differ compared to face-to-face services in the existing field of provision are also unknown. Further information, such as the education level of participants, or, more specifically, contraceptive knowledge, would be useful for understanding more about the capital associated with access to and effective use of the online service. Both education level and contraceptive knowledge are data which will be collected in the empirical studies in Chapters 7 and 8.

5.6.5 Implications

Some elements of the descriptive data for individual service-users has implications with regard to the sociodemographic characteristics of the target population. Both Lambeth and Southwark are ethnically diverse. In Lambeth 59% of the population describes themselves as White and 24% of Lambeth residents identify as black (Figure 2-7). In this study, 128 (17.6%) identified as being of black ethnic group out of the online service-users (n=726) and being of either the black, Asian or mixed ethnic groups were each associated with lower odds of repeat use when compared to those of white ethnic group (n=487). These are important findings, particularly for such an ethnically diverse target population, as they indicate that there may be barriers to access and repeat use of the online OCP services for large sections of the local community. Analysis of national data suggests that being of black or Asian ethnic groups have associations with lower use of effective contraception (8). National data also suggests that ethnic minority groups are more likely to use community clinics and less likely to access GPs for their contraception than white ethnic groups (70). Furthermore, in both boroughs, repeat abortions are more common among black African and black Caribbean women (189). Whilst the findings in this study may be expected in this broader context of poorer SRH outcomes for BAME groups, further investigation is recommended as they may be suggestive of ways in which the intervention could be further enhanced to better cater to the needs of the target population.

The majority of these service-users were aged between 20 – 24 years (37.5%) and 25 – 29 years (35.0%) which suggest that online contraception could appeal to the age groups for whom unplanned pregnancies occur most frequently (1). However, it is also important to consider that among the pregnancies occurring in adolescents in England, many are reportedly unplanned and over half result in abortions (190). The online service did not permit access to those under 18 years which is arguably a sound decision reflecting the need for adherence to guidelines around safeguarding when prescribing to young people (305). Despite this, a small proportion (9.0%) of service-users aged 16 – 18 years were found in the dataset (65/726), which was attributed to possible errors in the system during this early stage in the availability of the service (Howroyd C [Service Development Director] 2018, oral communication, 18th May). The finding has important implications when considering investment and commissioning of online services as they may be unable to meet the access needs of adolescent women.

The descriptive data also shows that 283 (39.1%) and 292 (40.4%) service-users are from the 1st and 2nd most deprived IMD quintiles. Southwark is ranked 40th most deprived out of the 326 national LAs, and is the ninth most deprived among the 33 LAs in London (188). Lambeth is ranked 44th most deprived out of the 326 national LAs and is the eight most deprived in London (47). More than 70% of LSOAs in Lambeth and Southwark are in the two most deprived quintiles (187) so this finding is a promising indication that those using the online service are reflecting the target population in terms of this measure of deprivation.

5.6.6 Directions for Future Research

The value in this study is in its capacity to be hypothesis-generating, with further research required to understand what characteristics are associated with access, use and repeat, effective use of the online OCP service. It is recommended that this analysis is repeated on a larger sample size, when the online intervention has been more widely and frequently used. This would enable regression analysis using ethnicity data for sub-categories rather than the broad ONS groups used in this chapter. It would also be useful to compare outcomes with OCP users accessing community clinics and general practice. Further research is also required to compare characteristics of regular OCP users in both face-to-face and online services, to women at risk of unplanned pregnancy who have unmet contraceptive needs.

In addition to making comparisons between the users of different service types, it is necessary to consider use of the online service within a larger field of contraceptive service delivery. The data in this study is not informative about the extent to which repeat and effective use of the online service is indicative of effective contraceptive use for pregnancy prevention where individual circumstances vary and access to alternative services is possible. For example, service-users may use the online service on one occasion to access OCPs temporarily, prior to obtaining a LARC method from general practice or community clinics, or service-users may forgo repeat ordering of OCPs during a period of sexual inactivity. In these hypothetical

examples, the data from online service-use alone would not be indicative of the effectiveness of individuals' access to contraceptive services overall. A study to determine patterns of service-use across the various delivery routes, and the reasons for continued use, altered use or termination of use is needed for a further understanding of these issues.

Chapters 6 and 7 contain the findings from a cohort study which compares outcomes between participants who used the online service for their first OCP prescription to those who used other community clinics and general practice for their first prescription. In addition to outcomes about short term continuation, Chapter 6 looks at patterns of service-use across the various delivery routes, the reasons for continued use, altered use or termination of use, which, along with the exploratory studies, facilitates greater understanding of the impact of the intervention on contraceptive practice.

5.7 Summary of Chapter 5

- During the initial 15 months of availability, the online service was accessed 1186 times by 726 unique individuals.
- The majority were aged between 20 and 29 years. Most were of white ethnic group and nearly 80% were residents of areas in the 1st and 2nd most deprived IMD quintiles.
- The majority of service-users made at least one complete order and almost a third made multiple complete orders. Time intervals between repeat orders indicated that 61% – 100% of service-users were experiencing adequate contraceptive coverage from their repeat OCP orders from the online service.
- In the comparison of service-users with repeat and non-repeat orders, the only covariate significantly associated with repeat use was ethnic group. Those of black, Asian and mixed ethnic group were less likely than those of white ethnic group to make repeat OCP orders from the online service; an association which was retained after adjustment for other sociodemographic variables.
- These are important initial findings on free-to-access, online contraception provision and indicate that further research should seek to understand whether certain sociodemographic groups in the target population are less likely to access and repeatedly use online contraceptive services and if so, why.

6 The Contraception in Person – Contraception Online (CiP-CO) Study: Impact Study

6.1 Chapter Overview

The cohort study presented in this chapter examines whether measures of short-term OCP continuation are associated with type of contraceptive service access among a population of new OCP users. The previous study described all those who used the online contraceptive service during its initial period of availability and found that those of black, Asian or mixed ethnic group were less likely than those of white ethnic group to make repeat OCP orders from the online service. The study in this chapter compares outcomes between participants who used the online service for their first OCP prescription to those who used other services, using both routinely collected service-use data and self-reported data via online questionnaires. These findings, in combination with the previous exploratory studies, facilitate a greater understanding of the potential impact of the online service.

6.2 Background and Rationale

The ToC model resulting from the qualitative study in Chapter 4 (Figure 4-2) conceptualised the positive processes of change predicted to ensue following the introduction of intervention into Lambeth and Southwark. This study emphasised that the evaluation needed to examine the outcomes in this model. Measuring the outcome of the rate of unplanned pregnancies would not be feasible given the rarity of pregnancy as an outcome and the time limitations of this thesis. The model depicted two distal outcomes: 1) Improved contraceptive continuation and; 2) improved uptake of contraception. In order to examine contraceptive uptake, one would require data pertaining to members of the target population with unmet need for contraception, not currently accessing contraceptive services. Therefore, this outcome was deemed better suited to a less time-constrained situation and at a later point in the online service's development, when there would be potential for greater awareness of the online service among the target population.

This study considers how measures of contraceptive continuation are associated with type of service among a population of OCP users during the first 15 months of the online service being available to residents of Lambeth and Southwark. OCP continuation is an important area for investigation as the majority of female contraceptive users opt for OCP above other methods and studies suggest that more than a third do not sustain the method beyond 3 months (73, 74). Women who discontinue their contraceptive method and either forgo or delay uptake of an alternative may be at risk of pregnancy if they continue to be sexually active (75, 93, 306).

The study in this chapter compares outcomes between participants who used the online service for their first OCP prescription to those who used other services, using both routinely collected service-use data and self-reported data via online questionnaires. These findings, in addition to

the previous exploratory studies, facilitate a more complex understanding of the impact of the intervention on contraceptive practice.

6.3 Aims and Objectives

The primary aim of this study is to examine whether measures of short-term OCP continuation are associated with type of contraceptive service accessed among a population of new OCP users. Comparisons are made between a population who access a novel, online contraceptive service for their first supply of OCPs and those who access their first supply of OCPs via existing, face-to-face services such as their local community clinics.

This study fulfils the following objectives:

- To describe proportions of participants who obtain a second pack of OCPs once their 3 months' supply of OCPs has expired, comparing outcomes between the different service groups (online contraception versus other services).
- To describe the timing of OCP continuation according to service data on time to repeat contraception prescription up to 4 months post-recruitment, comparing outcomes between the different service groups (online contraception versus other services).
- To describe the proportion of participants who remain at the service at which they initiated contraception according to service data up to 4 months post-recruitment.
- To describe participants' reasons for discontinuation of contraception.

6.4 Hypothesis

It is hypothesised that significantly more OCP users accessing SH:24 for their first 3 months' supply of pills will obtain a second pack of OCPs when compared to new OCP users accessing face-to-face services. The basis of this hypothesis is from the ToC Model (Figure 4-2), which predicts that online contraception can improve contraceptive continuation due to increased convenience, anonymity, autonomy and responsive support.

However, the ToC model also emphasises that these positive processes of change are dependent upon assumptions about how the target population would respond to the innovative service. Thus, the study is designed to collect data that reveals the characteristics, circumstances and motivations of the participants and tests whether any associations between the exposure and outcome are influenced by these factors.

6.5 Methods

6.5.1 Study Setting

The study began recruiting participants from contraceptive services situated in Lambeth and Southwark in October 2016. This chapter contains the results for participants recruited up to December 2017. The online contraceptive service, SH:24, was launched in January 2017 for residents of Lambeth and Southwark. It was not widely advertised or promoted during the study period. It should also be noted that SH:24's online STI testing service had been available for some time prior to this, since March 2015. It is therefore likely that the participants in this study using the online contraception service represent a unique group of individuals who became aware of this service prior to its wide promotion, possibly through use of SH:24's alternative services.

6.5.2 Recruitment

Recruitment strategies differed according to the service women accessed for their 3 months' OCP supply.

1) Online contraception intervention (SH:24)

All women accessing OCPs from SH:24 during the recruitment period were invited to participate in the study at the end of their online consultation when the dispatch of their delivery of OCPs had been confirmed. They were invited in the following ways:

1) A very brief synopsis of the study appeared on the SH:24 webpage with a link to the study website.
2) An invitation text was sent to all women who had ordered their OCPs from SH:24 with a link to the study website.
3) Those women who had not signed up from the online invitation or text would receive further texts to invite them to take part.

Examples of these promotional messages are provided in Appendix O. The study website contained the participant information sheet, contact information of those conducting the study and a list of eligibility criteria.

2) Other services

The first stage involved communicating information about the study to clinic, GP and pharmacy staff, particularly those who dispense contraception. Staff were encouraged to give patients who they considered to be eligible information about the study, a leaflet (Appendix P) or card (Appendix Q) with the study information and the opportunity to consent to being contacted by a research assistant within the next seven days. These patients would then be able to access the study website using the link on the card or leaflet or be invited to the study via a phone call or text message. Additional promotional information was distributed around the clinic and attached to pill packets (Appendix Q). These contained the address of the study website.

To boost recruitment, at intermittent stages the strategy of personally inviting patients to take part in the study was carried out by the study coordinator or research assistant (RA) presenting patients with study information and eligibility criteria using paper forms or a tablet following a referral from clinical staff. They had the choice to enrol in the study there and then or to receive a link to the study website to read the information without the presence of the RA and take more time to consider participation (up to 4 weeks after obtaining their OCPs).

3) Recruitment in the community

Additional recruitment took place in the community through targeted, online advertising and KCL mass emails.

6.5.3 Participants and Data Collection

Self-reported and objective data collection points are depicted in relation to the point of recruitment of participants in Figure 6-1.

New OCP users were defined as those who had obtained their first 3 months' supply no later than 4 weeks prior to enrolment and had not taken OCPs within the past month of initiating this supply. Participants were invited to participate in the study immediately after their OCP consultation. Should they have agreed to the requirements of the study after reading the participant information sheet (Appendix L) and consented to the conditions of the study via the consent form (Appendix M), they provided their name, telephone number and further contact information via a brief self-reported questionnaire delivered online using the study website (see Appendix N for screenshots of the study website) or face to face depending on the circumstances of recruitment. Objective data was used to verify participants' attendance at the service in which they were recruited or in which they self-reported their attendance.

Six days later they received a text to direct them to the first online questionnaire. Participants were able to follow the link in the text message to complete the questionnaire on their smartphones or request that the link be sent via email or through the post. Details of the content of the questionnaire are described below and in Table 6-1.

After the 3 months' prescription of OCPs had expired, participants' service-use was followed-up for a further 1 month to establish the point at which they obtained their next contraceptive prescription and which service they accessed to get it. Those who did not obtain a new OCP prescription within this 1 month time frame were considered discontinuers, following the definition of contraceptive discontinuation by Stuart et al. (2013) (307). In addition, service records were used to determine the percentage of participants who accessed alternative methods i.e. Cu-IUD, IUS, patch, injection, vaginal ring, sterilisation and diaphragm and the proportion who self-reported use of condoms or withdrawal. Additional self-reported data were obtained via online follow-up questionnaires at 4 months. Discrepancies between self-reported

data and objectively measured data on contraceptive continuation and service-use were recorded.

In order to reduce loss to follow-up of self-reported data via the online questionnaires sent at 6 days and 4 months post-recruitment, researchers contacted non-responders to remind them to take part. The procedure for this was refined through the recruitment process with text reminders sent at a week past the initial request for completion and then every few weeks until the second questionnaire was due, at which point reminders were sent out for both questionnaires to be completed. In addition to text messages, phone calls were made intermittently and if email addresses were provided, these were also used to contact non-responders. At each point of contact, participants were reminded of the value of the study and the cash incentive they would receive upon completion of the questionnaires (£5 following completion of the first questionnaire at 6 days post-recruitment and £10 following completion of the second questionnaire at 4 months post-recruitment). In the event that non-response was ongoing after several attempts at contact, participants were sent a text offering them termination of their participation in the study.

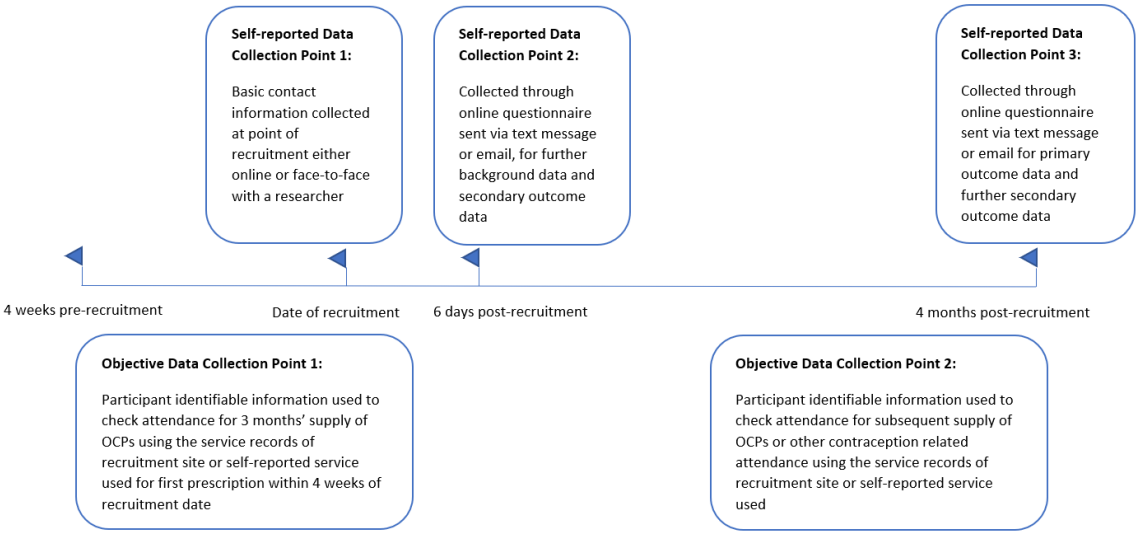


Figure 6-1 Data Collection Points
Oral contraceptive pills, OCPs

Points of data collection are depicted in Figure 6-1. Objective data sources were the records of service-use from the contraceptive services through which participants were recruited, or alternatively, the services named by participants as the service they used for either their first or second supplies of contraception.

1) Camberwell Sexual Health Clinic (CSHC)

CSHC was the main service through which participants were recruited for the exposure of "other service". This is a busy community clinic situated in Camberwell, Southwark. The data manager for CSHC was provided with a list of names, DOB, mobile numbers

and postcodes of all participants to check attendance for contraception activity at the service since October 2016. This produced two spreadsheets. Firstly, one that indicated if a participant had been found to have a CSHC clinic ID, or multiple clinic IDs. The second listed dates of attendance and codes of their activity at each date, coded according to the Sexual and Reproductive Health Activity Dataset (SRHAD). Where participants had multiple clinic IDs, SRHAD codes had to be matched against one individual. All participant data in the study dataset was coded using a unique coded ID in order to maintain ethical procedures of separate storage of identifying data and questionnaire and contraceptive activity data. Thus, incorporating CSHC clinic data into the study database required a two-stage process, firstly to link SRHAD data to individual participants and then to link data to the participants' study unique IDs.

2) Guy's & St.Thomas' Trust (GSTT) SRH services

Recruitment also took place in GSTT services including Burrell Street Sexual Health Service, Streatham Hill Clinic and Walworth Road clinic. The data manager for these services conducted a search of all study participants in the same way as described for the CSHC data search above. The data source returned for analysis listed SRHAD data by date with individuals identified by name. The dataset was matched according to the study unique ID so that identifiable data could be removed and the GSTT objective data could be merged onto the central study database.

3) General Practice and other Face-to-Face Services

Certain GPs and other face-to-face services needed to be contacted to search for attendance data for those participants that named contraceptive service outside of CSHC, GSTT SRH services and SH:24 for either their first or second contraceptive supply. The self-reported data was consulted to create a list of services to contact. Services were contacted via email, post and, if no response was forthcoming, they were followed up with a phone call. Services were sent details of the study, including the participant information sheet, evidence of ethical approval and participants' online consent forms. It was requested that they checked that the named participant had attended for contraceptive services from one month prior to their recruitment date up to the date that contact with the service was made. Services were asked to complete a form confirming that the participant had attended and then listing the date and type of contraceptive service accessed at each date. Responses were recorded in a database and then merged onto the central study database using the study unique ID.

4) The Intervention: SH:24's Online Contraception

The data source utilised for the study in Chapter 5 was used again for this study to search for CiP-CO participants. This SH:24 dataset was searched using participants'

DOBs and postcodes. Additional manual checks were conducted on other variables such as ethnic group and self-reported dates of attendance for those recruited from SH:24. As with other data sources, SH:24 data was matched to the participants' unique IDs and merged onto the central study database.

A combination of objective and self-reported data were used to determine outcomes for the CiP-CO study. Participants were asked to complete self-reported questionnaires at three stages during the study period.

1) Data Collection Point One

This brief survey is provided in Appendix D. Participants were asked to list their name, DOB, mobile number, address and postcode. From February 2017 the study was amended so that participants were also asked to list the site at which they were recruited. Participants recruited face-to-face with a researcher used paper forms to provide this data and those recruited remotely followed a link to the specially designed study website (Appendix N) that collated the data using the SH:24 secure server.

2) Data Collection Point Two: "Questionnaire One"

This questionnaire was developed to collect background data on participants. In addition, it collected secondary outcome data on basic OCP knowledge and service ratings (presented in Chapter 7). The full questionnaire can be seen in Appendix E. The questions for the study were determined firstly, through literature searches to ascertain factors that have been associated with unplanned pregnancy and effective contraceptive use and secondly, on the results of the ToC study which predicted that the positive effects of the online service could vary according to individual characteristics and the timing and circumstances of their need for contraception (Table 6-1). In addition, questionnaires from similar contraception studies were referred to where possible and adapted for use where fitting. Face validity of the questionnaires were tested through piloting with females of reproductive age in the waiting room of CSHC and content validity was enhanced through ensuring that the questions had grounding in the literature. Questions were designed to collect data across 5 domains: 1) Sociodemographic information; 2) Reproductive and contraceptive history; 3) Motivations around pregnancy prevention and OCP use; 4) Service feedback and; 5) Basic OCP knowledge.

Table 6-1 Background Data Collected in the Questionnaire sent to Participants at 6 days Post-Recruitment

Domain	Questions	Literature	Theory of Change Study	Study design
Contact details	- Name - Email - Mobile number - Address	-	-	- To contact participant and send online questionnaires - Identifiable variables used to search routinely collected datasets from services
Descriptive data	Date of birth (age)	- Age associated with type of contraceptive service accessed (70) - Young age associated with mistimed pregnancies and adverse outcomes related to unplanned pregnancies (51, 308) - Age associated with preferences for online health services (31, 301)	- Age predicted to be associated with preferences for online services and remote contact with service provider - Age predicted to be linked to vulnerable service-users and/or more complex needs	- Identifiable variables used to search routinely collected datasets from services - Postcode used to check eligibility - Address and postcode required for postage of cash incentive and questionnaires where requested
	Postcode	- Used to obtain Index of Multiple Deprivation (IMD): multi-dimensional measure of area-level deprivation. Area-level socioeconomic disadvantage associated with contraceptive-use (54)	- Socioeconomic status may be one type of circumstance influencing access to and effective use of online contraception, particularly in Lambeth & Southwark with its pockets of deprivation - Full-time employment is a barrier to access of face-to-face services during their typical opening times	
	What is your employment status?	- Further measures to add to postcode for an overview of socioeconomic status - Sexually active women from minority ethnic groups less likely than white women to use effective methods of contraception (8) - Unplanned pregnancy associated with lower educational attainment (1, 308) - Women with lower levels of formal education less likely to use contraception (54)		
	Which of the following best describes your ethnicity?			
	What is the highest education level you have or are currently studying for?			
	Are you a smoker?	- Unplanned pregnancy associated with current smoking status (1) - Smoking associated with willingness to take risks in the health domain (309, 310)	-	
Reproductive and contraceptive history	Is this the first time you have been given oral contraceptive pills?[†]	- Past use associated with women's intentions to use contraception (253) - Starters more likely than switchers to discontinue contraception(306)	- More experienced oral contraceptive pill (OCP) users may prefer remote services as they require less support that completely new OCP users – who may also be likely to be younger	
	What is your main reason for accessing the pill?	- Motivation to prevent pregnancy is associated with use of contraception (254, 255)	- The online service might attract more motivated OCP users, particularly during the early	

Domain	Questions	Literature	Theory of Change Study	Study design
			stages of its availability	
	Are you sexually active?	- Unplanned pregnancy associated with higher frequency of sexual intercourse (1)	- Use of online service likely to shift with time and circumstance - Partners may influence effective use of online service - Busy family lives may influence preferences for online services either positively or negatively	
	How many sexual partners have you had in the last year?			
	Do you have a regular partner?	- Risky contraceptive behaviours associated with not being in a current relationship (255)		
	Have you ever been pregnant?††	- History of an unplanned pregnancy is a predictor of unintended pregnancy (308)		
	Do you have children?††			
	Have you ever had an abortion?††			
	In the past year have you had unprotected sexual intercourse at a time you did not want to become pregnant?	- Adolescent mothers report recent unprotected sexual intercourse (311) - History of inconsistent contraceptive use is a predictor for future inconsistent contraceptive use (312)		
	In the past year have you taken emergency contraception?			
Motivations around pregnancy prevention and OCP use	How likely do you think it is that you will use the pills you have been prescribed?†††	- Adapted from an item in the Contraceptive Utilities, Intention, and Knowledge Scale (CUIKS) designed to measure intention to use contraception (313)	- The online service might attract more motivated OCP users, particularly during the early stages of its availability	
	If you keep taking the pill, how likely do you think it is it that you will become pregnant within the next year?†††	- Adapted from an item in the CUIKS designed to measure perceived likelihood of effectiveness of contraception and perceptions of fertility		
	How do the people who are most important to you feel about your using the pill?†††	- Adapted from an item in the CUIKS designed to measure the subjective social support expected for use of OCPs		
	How would you feel about becoming pregnant within the next year?†††	- Adapted from an item in the CUIKS designed to measure attitude about becoming pregnant at the present time - Perception of the severity of pregnancy associated with intentions to use contraceptives (253) - Motivation to prevent pregnancy is associated with use of contraception (254, 255)		

• Some routine questions, e.g. those verifying place and date of attendance, not included)

†Those who have previously been prescribed OCPs were also asked if this was within the past year or more than a year previously

††Participants also asked about the frequency of these events

† ††Use of Likert scale to register a spectrum of categorical responses

1) Data Collection Point Three: "Questionnaire Two"

This questionnaire was designed to determine the participants' contraceptive journey since their first prescription of OCPs (Appendix F). This required consideration of the various potential pathways a new OCP-user may take including not taking the OCPs originally prescribed, switching to an alternative method either before or after the original OCP prescription had expired, discontinuing contraception completely or opting for a less effective method like condoms. Other secondary outcome data were also collected in this questionnaire including the following: whether the participant remained at the service at which they got their initial OCP prescription and if they changed, the reasons for this; their reasons for discontinuing contraception; and whether they had experienced any pregnancy risks during the study period and what action, if any, they took as a result of this. There were some additional open-ended questions requesting feedback on the CiP-CO study and on contraceptive services in Lambeth and Southwark explored in Chapter 7 and Appendix S.

Further Details on Questionnaire Development

Both questionnaires went through several iterations before the final design and set of questions were finalised. The process of refinement involved testing and collating feedback from the internal research team involved in SH:24 evaluation work, testing among CSHC staff including contraceptive clinicians, and at the final stage, through testing with CSHC service-users who were asked to read the questionnaire and give their feedback whilst they were in the clinic waiting room. Although these CSHC service-users were not asked if they met the study inclusion criteria, they were considered to be potential participants as they were female, of reproductive age and attending a Lambeth SRH service.

Online Delivery of Questionnaires

Questionnaires were delivered using the online data collection tool, Typeform. This enabled the questionnaires to be designed with in-built skip patterns and comprehensive option lists. The questionnaires were built to be simple and easy to use for participants completing the questionnaires on their smartphones, laptops or other devices. The platform was linked to the central study database so that unique IDs could be automatically generated and embedded in the links sent to participants. The central study database was developed to automatically text the links to the questionnaires at 6 days and 4 months after the recruitment date of each participant. Maintaining the use of unique IDs throughout this process meant that Typeform did not hold any identifiable data.

6.5.4 Exposure

The exposure was defined as the service that was accessed for the participants' first consultation and prescription of a 3 months' supply of OCPs.

Exposure 1: Intervention - Online Contraception (SH:24)

Participants recruited after ordering OCPs from the online contraception service, SH:24, were considered to be subject to the intervention exposure (exposure 1). For further details of the online service and the ordering process, see section 2.10 and Appendix C.

Exposure 2: Other Services – Community Clinics and General Practice

Exposure 2 was access to a first prescription of a 3 months' supply of OCPs from community clinics, pharmacy and general practice, i.e. face-to-face services that existed in the pre-intervention environment. Community clinics and general practice typically provide the full complement of contraceptive methods, usually available via a walk-in system for the former and an appointment system for the latter. In community clinics, OCPs are given directly to the patient should they meet the eligibility criteria for the supply. In general practice, OCP prescriptions are given to the patient, which they then take to a pharmacy to obtain their supply. The consultation for new COC users usually involves a BP and BMI check and counselling about the chosen method. A prescription for POP does not typically involve a BP or BMI check but all other aspects of the consultation are necessary, particularly counselling around side effects.

6.5.5 Sample Size Calculation

It was intended that the study should be powered for the primary outcome which was the proportion of OCP continuers in each group (exposures 1 and 2). A minimum recruitment of 780 clients (390 per group) was estimated to obtain at least 80% power to detect an increase of 10% in OCP continuation in the SH:24 group compared to the group using existing contraceptive services, based on a two-sided test with a 5% significance level. This sample size estimation makes the conservative assumption that OCP continuation in the face-to-face services group would be 65%, based on studies reporting contraceptive use in face-to-face services (44, 73, 78, 93, 314). The sample size had been adjusted to account for loss to follow-up (15%). It was estimated that recruitment would take 9 - 12 months at a rate of approximately 50 - 100 per month based on SH:24 projections and service use in Lambeth and Southwark.

6.5.6 Inclusion and Exclusion Criteria

Potential participants were subject to inclusion criteria. In face-to-face services clinicians were made aware of all criteria, but in recognition of clinician's competing priorities in busy services, were asked to simply refer service-users who were attending for a 3 months' supply of OCPs to either the study website or to researchers stationed in services. Where researchers were present, they asked participants to confirm that they met the full list of criteria. Where recruitment took place remotely, participants had to self-select their inclusion criteria and could not continue to the consent and sign-up pages if they did not meet all of these. In order to reduce the potential for illegitimate self-selection of inclusion criteria, all participants attendance for a 3 months' supply of OCPs were checked against service records and removed should the records indicate non-eligibility.

Inclusion Criteria

1. Resident of Lambeth or Southwark.
2. Prescribed with their first 3 months' supply of any brand of COC or POP from any service no later than 4 weeks prior to enrolment and verified using objective data (service records).
3. Aged 16 years or above.
4. Independent access to a mobile telephone.

Exclusion Criteria

1. Those who are repeat OCP users i.e. have taken the same brand of OCPs from the same service within the 4 weeks preceding their latest OCP supply.
2. Those who have been prescribed OCPs whilst already using a LARC method, e.g. to regulate bleeding patterns that have been affected by the insertion of a LARC.
3. Those unable to read in English as the study website was in English.
4. Those unable to give informed consent, such as people with severe learning difficulties.

6.5.7 Outcomes

The primary outcome was measured objectively using routinely collected data on service-use. The time points of measurement were at the point of recruitment, then up to 4 months post-recruitment. These time points were chosen to best measure contraceptive continuation in accordance to FSRH guidance that states that a follow-up visit 3 months after the first prescription of OCPs is advised, at which point women may be reassessed and prescribed further contraceptive supplies, which in the case of OCPs, was likely to be another prescription of 6 or 12 months (83).

Primary Outcome

1. % participants who continue to their second pack of OCPs according to service data on OCPs prescribed from up to 4 months post recruitment.

Secondary Outcomes

1. Time in days until OCP continuation i.e. when the participant accesses her next OCP supply according to service data on contraception prescribed up to 4 months post-recruitment.
2. % participants who remained at the service at which they initiated contraception according to service data up to 4 months post-recruitment.
3. % participants who obtained a prescription of an alternative (not OCPs) method of contraception.

- % participants obtaining each of the different types, i.e. implant, IUS, IUD, injection, patch, vaginal ring, diaphragm, sterilisation.

4. % participants who discontinued contraception and self-reported use of male/female condoms or withdrawal.
5. Self-reported reasons for contraceptive discontinuation:
    - % discontinue due to method e.g. side effects.
    - % discontinue due to service.
    - % discontinue for other reasons including pregnancy, a desire to become pregnant or no longer needing contraception.
6. % participants self-reporting unprotected sexual intercourse (UPSI) during the study period and not wanting to become pregnant.
    1. % experiencing unplanned pregnancy.
7. Self-reported rating scores of experiences of accessing contraception.

6.5.8 Background Variables

Age (years): Participants provided their DOBs at enrolment. The date of birth and date of recruitment was used to generate the age of the service-users.

Ethnic group: All participants were asked to submit their ethnicity in the first section of the questionnaire completed at 6 days post-recruitment. To maximise the potential for power during the analysis stage, ethnicity categories were collapsed into ONS categories; i.e. white, black, Asian, mixed ethnicity or other (302).

Index of Multiple Deprivation (IMD): Participants provided their postcode at enrolment. The postcode lookup tool from the Ministry of Housing Communities & Local Government website was used to acquire deprivation data at LSOA level. The relevant data was the IMD decile which was downloaded according to the user id variable and then merged back onto the original dataset. The decile categories were collapsed into quintiles to increase the likelihood of adequate power at the analysis stage.

Education level: All participants were asked to submit the highest education level that they had achieved or were studying for through selection of a list of qualifications taken from the Regulated Qualifications Framework (RFQ) and Framework for Higher Education Qualifications (FHEQ) (315) in the questionnaire sent at 6 days post-recruitment. The RFQ and FHEQ categorises qualifications from entry level to level 8, grouping them according to their level of difficulty. The qualifications were further collapsed into three categories from the lowest to highest levels.

Employment: All participants were asked to submit their employment status in terms of whether they were employed, unemployed, a student or parent or carer at 6 days post-recruitment. Participants could select more than one status, but to add strength to the analysis, all responses

were eventually categorised as employed, unemployed (including parents or carers), student and finally those who were both students and employed.

Further background variables: Further background variables and the rationale for their inclusion in the study are provided in the description of the questionnaire data sources and Table 6-1.

6.5.9 Outcome Variables

Continuation of OCPs: The primary outcomes was a binary variable. Participants were recorded has having continued their OCPs based on the objective service records at either the service they had attended for their first supply of pills at recruitment or the service they named in their self-reported questionnaires. The definition of continuation for this study was a prescription date for a second pack of OCPs within 4 weeks of the first prescription of OCPs expiring (307). OCP continuers were those who:

- Had visited a service for a supply of OCPs within 4 weeks of their first OCP prescription expiring according to objective data from service records.

OCP discontinuers were those who:

- Had a record of attendance for alternative, effective methods of contraception.
- Self-reported discontinuation with no record of attendance for contraceptive methods at the service they originally attended for OCPs.
- Self-reported continuation but with no record of attendance for contraceptive methods at the service they originally attended for OCPs, or a record of attendance for contraceptive methods more than 4 months after enrolment in the study.
- Had either objective or self-reported data that their chosen form of contraception after their first OCP prescription were either condoms or withdrawal (methods which were not considered effective contraception within this study according to typical use percentages from the FPA (316)) with no additional form of pregnancy protection.

Time from first OCP prescription expiry until second OCP prescription: This was a continuous variable, measuring time from first OCP prescription expiry until the second OCP prescription in days. Objective data, using the dates of attendance for OCPs within the service records of participants, was used to determine the time interval. Firstly, the predicted date of the first prescription expiry was determined through the addition of 84 days to the date of attendance for the first supply of OCPs. Then, the date of the subsequent attendance for OCPs was subtracted from the predicted date of expiry to determine the interval.

Continuation of any effective method of contraception: This too was a binary variable and collected in the same way as the continuation of OCPs, through checking service records at either the service they had attended for their first supply of pills at recruitment or the service they named in their self-reported questionnaires. Service records were checked for the date of attendance, as this needed to be within 4 weeks of the first prescription of OCPs expiring

(following the definition of contraceptive discontinuation by Stuart et al. (2013) (307)), and the reason for attendance. Effective methods included OCPs, LARC and other methods with a typical use failure rate below 10% according to the FPA (316). Those self-reporting condom-use or with objective data pertaining to their attendance at a service for condom-use, were also considered discontinuers within this variable. In addition, participants reporting use of withdrawal and other methods with a typical use failure rate above 10% according to the FPA, were also considered discontinuers.

Type of contraception continued: This binary variable looked at the proportion of participants who accessed a service for each of the possible alternative methods of contraception during the study period. Service records were used where the attendance was for an alternative, effective method of contraception, but where service-users self-reported condom-use verification with objective data sources was not carried out as condoms are often purchased from private providers (70) which were not possible to contact in this study.

Reasons for discontinuation: This was a categorical variable, grouping responses from the self-reported questionnaire according to whether the reasons provided were due to concerns with perceived side-effects of contraception, preferences for alternative methods, i.e. condoms or withdrawal, dissatisfaction with the contraceptive service, personal circumstances such as not being sexually active or wanting to become pregnant. Those participants who self-reported continuation, but who's service records had a record of attendance for effective contraception beyond 4 weeks of their first prescription expiry, were recorded as having a late prescription as their reason for discontinuation. The initial categories were chosen during questionnaire development to reflect reasons for discontinuation described in the literature (79, 306). There were some participants for whom the reason for discontinuation was unknown, including those who's self-reported continuation was contradicted and overridden by the objective data.

Service switching: This was a binary variable recorded according to whether the objective data for contraceptive continuation was from the original service used for the first supply of OCPs at recruitment, or at an alternative service. Those self-reporting attendance at a different service without the objective data to verify this, were not included in the variable.

Pregnancy risk during study: This binary variable was determined through combination of the self-reported responses to questions on UPSI during the study period and pregnancy risks occurring due to missed pills.

Action taken as a result of pregnancy risk: This categorical variable recorded the different types of action taken as a result of a pregnancy risk during the study. All participants who reported a pregnancy risk were also asked about what action they took as a result of this, selecting from options to determine whether they returned to the service they used for their first supply of OCPs to seek advice from a health professional, whether they attended an alternative service, used a leaflet, used the internet or took no action at all.

6.5.10 Exposure Variables

Prescription of 3 months' supply of OCPs at service: Service records at the services used as recruitment sites were used to determine whether participants had attended an online service or face-to-face services for their prescription of 3 months' supply of OCPs. Participants were recorded as either having attended the online service or at any other service, with all community clinics and GP services combined into this latter category. Although the implementation of inclusion criteria was intended to prevent entry into the study for those who had not been subject to this exposure, verification using the objective data led to the removal of participants prior to analysis if data was missing or there was not a record of service-use for 3 months' of OCPs at the recruitment site or site named by participants as their point of access.

Date of attendance for 3 months' supply OCPs: Service records at the services used as recruitment sites were also used to determine if participants had attended for their 3 months' supply of OCPs at a date that was within 4 weeks of the date of recruitment. Although the implementation of inclusion criteria was intended to prevent entry into the study for those who had a date of attendance outside of this time period, verification using the objective data led to the removal of participants prior to analysis if data were missing or the record of service-use for 3 months' of OCPs was outside of the date required for inclusion.

6.5.11 Missing Data

Participants were removed from the analysis if objective data for their first attendance of OCPs during the time period specified by the inclusion criteria was missing i.e. no record of attendance at the service participants stated they accessed their first prescription of OCPs or the service did not provide the data (either because contact could not be made, the service did not reply, or the service declined to provide it). Background data collected at the first and second self-reported data collection points were presented regardless of availability of primary outcome data. In the presentation and analysis of outcome data, participants with missing data on continuation or discontinuation were removed. Participants with missing primary outcome data were those who:

- Had no service records of attendance for contraception at the service they stated they had used for contraception in their self-reported data.
- Had no service records of attendance for contraception at the service they stated they had used for contraception in their self-reported data either because contact could not be made with the provider, the service did not reply when contacted or the service declined to provide it.
- Did not complete their self-reported questionnaire at 4 months and did not have any record of attendance at either SH:24; CSHC clinic or GSTT SRH services.

6.5.12 Analysis

1) Descriptive data were provided on recruitment, numbers assessed for eligibility compared to numbers actually recruited and completeness of follow-up.
2) Sociodemographic characteristics and other background variables were described for the study population and any differences between the online group and other services group determined through bivariate analysis.
3) Descriptive data, mean differences and ORs for the outcome of OCP continuation were determined for all participants at 4 months follow-up. Odds ratios and risk differences were calculated to identify differences between the exposure of type of service used for OCPs (online or other) and the primary outcome of OCP continuation at a 5% significance level.
4) An a priori decision was made to conduct a logistic regression analysis to examine the strength of the association between type of service and OCP continuation in the presence of ethnic group and all other available sociodemographic variables, i.e. age group, IMD quintile, employment status and education level, at both the bivariate and multivariable level. This was to determine if any association between type of service and OCP continuation would be retained in the presence of these other variables, in particular ethnic group, which was found to be associated with the outcome of repeat use of the online service (Chapter 5). This was also in acknowledgment of the literature (presented in section 2.6) which reported links between ethnicity and other sociodemographic factors and effective use of contraception (8, 54, 145). Logistic regression was also performed to examine the strength of association between type of service used and other background variables collected via the questionnaire. Those variables that were significantly associated with type of service used at the bivariate level with a p value <0.05 were also adjusted for in the multivariable analysis to test the association between type of service and OCP continuation in the presence of these additional variables.
5) Continuous data on the outcome of time from first OCP prescription expiry to second OCP prescription was subject to a test for normality. A non-normal distribution resulted in a test of difference in medians between exposures.
6) Proportions accessing OCPs at each week since first prescription expiry were calculated as cumulative percentages according to exposure to depict differences in access over time.

All analyses were conducted with the use of STATA V.14.1 (StataCorp).

6.5.13 Ethical Considerations

Ethical approval for this research was granted by Dulwich Research Ethics Committee (reference: 16/LO/1025) (Appendix T).

All participants were provided with online information about the study via the study website. The site also provided details of the study coordinator so participants had a person to contact should they require further information. Participants were informed that they could withdraw from the study at any stage.

The questionnaire data collection at baseline and follow-up was coded. Personal details were stored on a password-protected computer held on a secure server at King's College London. This information was stored separately from any anonymised research data. The study has not yet terminated but all data will be stored until two years after the study ends at which point it will be securely deleted and destroyed.

6.6 Results

In total, 227 participants were recruited, 77 (33.9%) of whom were subject to the exposure of the intervention of online contraception and 150 (66.1%) who were subject to the exposure of other contraceptive services. All 227 were verified as having attended a contraceptive service for a 3 months' supply of OCPs within 4 weeks of being recruited to the study.

The recruitment period was over-estimated and is currently ongoing. The time frames to reach the sample size necessary for adequately powered analysis of primary outcomes have been extended beyond that which is possible for the outcomes to be reported within this PhD thesis. Therefore, data on participants who had been recruited prior to the end of 2017 were extracted and analysed, the results of which are presented in the tables that follow.

As shown in Figure 6-2, in total, 227 people were included in the final dataset having been recruited into the study and having provided at least their DOB, address and postcode and further contact details (mobile number and email address). Primary outcome data on OCP continuation were available for 42 out of 77 participants from the online service (54.6%) and 87 out of 150 participants from other services (58.0%). 182 (80.2%) went on to complete or partially complete their first questionnaire at 6 days post recruitment and 146 (64.3%) went on to complete their second questionnaire at 4 months post recruitment. The primary objectives required analysis of objective data from participants' service records. A total of 129 participants were included in the analysis for the primary outcome of the proportion continuing OCPs, which included 66 (51.2%) individuals for whom their contraceptive use could be verified from service records and 63 (48.8%) who self-reported discontinuation of any effective method of contraception (including those self-reporting a method switch to condoms or withdrawal) and those who self-reported continuation but whose service records showed that their subsequent prescription was more than four months after their first prescription. Out of these 129 participants, 6 (4.7%) did not provide any data for their first or second questionnaires and 16 (12.4%) did not provide any data for their second questionnaires, therefore these participants have only partial background data available and their outcome variables are based on objective data alone.

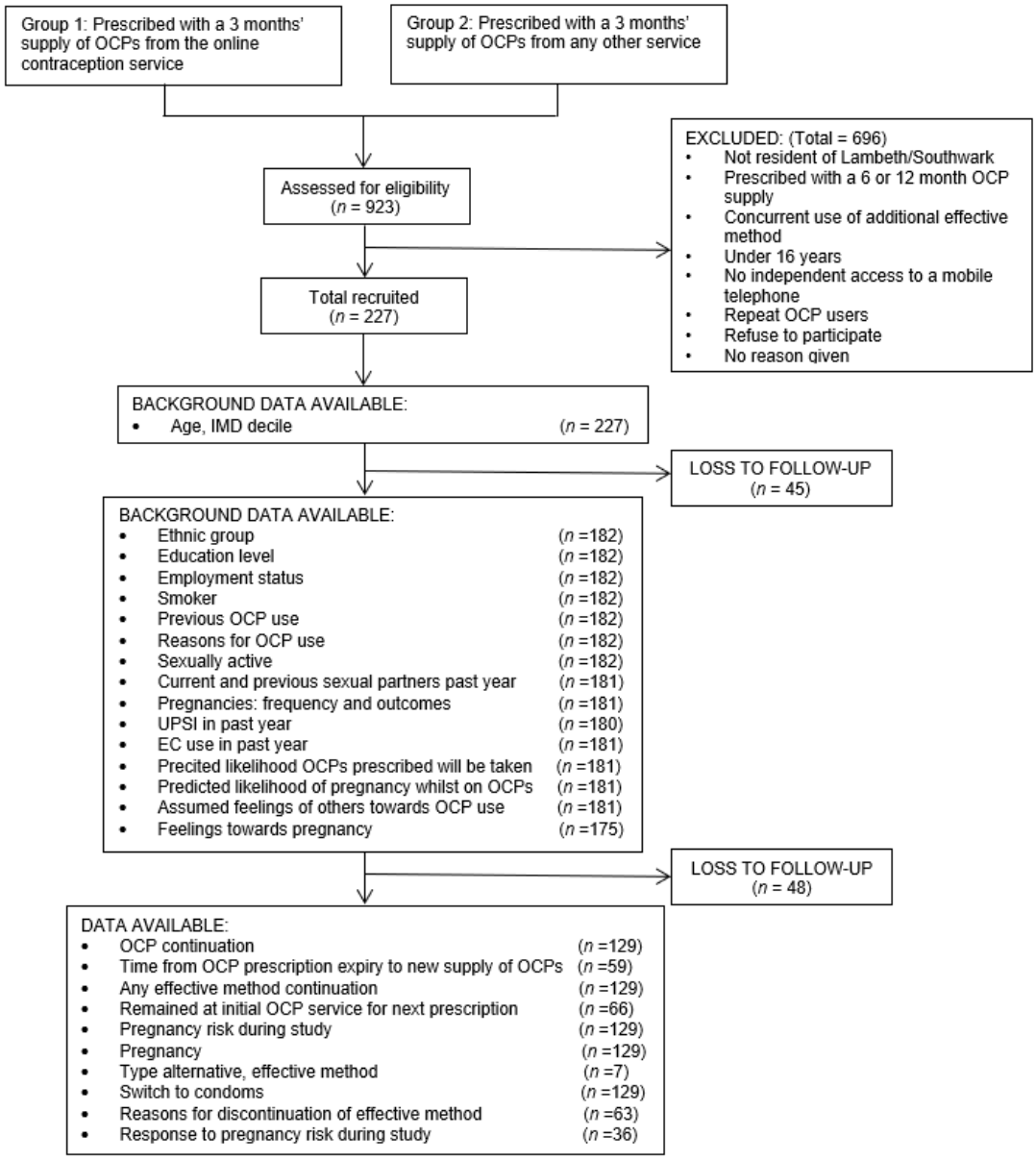


Figure 6-2 Study Flow Diagram

Oral contraceptive pills, OCPs; Index of Multiple Deprivation, IMD; unprotected sexual intercourse, UPSI; emergency contraception, EC

6.6.1 Background Data for all Participants

Sociodemographic data for all 227 eligible participants is provided in Table 6-2. There were no statistically significant differences in characteristics between the online contraception (n=77) and other services group (n=150). However, there was some indication that a greater proportion of 'other service' users were aged 16-19 years compared with the online contraception service-users.

Table 6-2 Sociodemographic Characteristics for all Eligible Study Participants Comparing Online Contraception Users to Other Service Users (n = 227)

	Online contraception (SH:24) (n=77)		Other services (n=150)			
	%	95% CI	%	95% CI	N	p value (X^2)
Age group (years)						
16 - 19	7.8	(2.9 – 16.2)	20.7	(14.5 – 28.0)	37	0.062
20 – 24	42.9	(31.6 - 54.7)	38.0	(30.2 – 46.3)	90	
25 – 29	33.8	(23.4 – 45.5)	24.0	(17.4 – 31.7)	62	
30 +	15.6	(8.3 – 25.6)	17.3	(11.7 – 24.4)	38	
Ethnic group†						
White	61.9	(48.8 – 73.9)	52.1	(42.8 – 61.3)	101	0.593
Black	20.6	(11.5 – 32.7)	22.7	(15.5 – 31.3)	40	
Asian	6.4	(1.8 – 15.5)	7.6	(3.5 – 13.9)	13	
Mixed	9.5	(3.6 – 19.6)	11.6	(6.6 – 19.0)	20	
Other	1.6	(0.0 – 8.5)	5.9	(2.4 – 11.7)	8	
IMD						
1st quintile (most deprived)	41.6	(30.4 – 53.4)	39.3	(31.5 – 47.6)	91	0.131
2nd quintile	35.1	(24.5 – 46.8)	44.7	(36.6 – 53.0)	94	
3rd quintile	20.8	(12.4 – 31.5)	10.0	(5.7 – 16.0)	31	
4th quintile	2.6	(0.3 – 9.1)	4.7	(2.0 – 9.4)	9	
5th quintile (least deprived)	0.0	(0.0 – 4.7††)	1.3	(0.2 – 4.7)	2	
Education†						
Entry Level – Level 2	7.9	(2.6 – 17.6)	5.9	(2.4 – 11.7)	12	0.769
Level 3 - 5	23.8	(14.0 – 36.2)	27.7	(19.9 – 36.7)	48	
Level 6 - 8	68.3	(55.3 – 79.4)	66.4	(57.2 – 74.8)	122	
Employment†						
Employed	54.0	(40.9 – 66.6)	47.9	(38.7 – 57.3)	91	0.423
Student & Employed	12.7	(5.7 – 23.5)	10.1	(5.3 – 17.0)	20	
Student	25.4	(15.3 – 37.9)	37.0	(28.3 – 46.3	60	
Unemployed	7.9	(2.6 – 17.6)	5.0	(1.9 – 10.7)	11	

Confidence interval, CI; Index of Multiple Deprivation, IMD

†45 missing values for Education, Ethnic group and Employment (online contraception n=63; other services n=119)

††one-sided, 97.5% CI

There was a reduction in the data available for further background variables presented in Table 6-3 due to loss to follow up between recruitment and the first questionnaire. There was a statistically significant difference (p=0.028) in the proportion of participants' self-reporting that they were smokers in the online contraception group (17.5%) compared to the other services group (32.8%). There was also a significant difference (p=0.019) in the Likert scale responses to the likelihood that OCPs prescribed would be taken with 96.8% of the online contraception group responding positively compared to 82.2% of the other services group. While there were no other statistically significant (at $p<0.05$) differences between the two service-type groups according to the other background variables examined, a few were indicative of a potential difference. For example, 55.0% of people in the other services group reported taking EC in the past year compared to 39.7% of people in the online group, however, this was not statistically significant (p=0.097) which may be due to the small numbers available for analysis.

Table 6-3 Background Data Collected in Questionnaire sent 6 days Post-Recruitment Comparing Online Contraception Users to Other Service Users (n=182)

	Online contraception (SH:24) (n=63)		Other services (n=119)			
	%	95% CI	%	95% CI	N	p value (X^2)
Smoker						
Yes	17.5	(9.1 – 29.1)	32.8	(24.5 – 42.0	50	0.028*
No	82.5	(70.9 – 91.0)	67.2	(58.0 – 75.6	132	
Previous OCP use						
No previous OCP use	22.2	(12.7 – 34.5)	27.7	(19.9 – 36.7	47	0.556
Previous OCP use in past year	49.2	(36.4 – 62.1)	41.2	(32.2 – 50.6	80	
Previous OCP use more than a year ago	28.6	(17.9 – 41.4)	31.1	(22.9 – 40.2	55	
Reason for OCP use						
Pregnancy prevention	79.4	(67.3 – 88.50	86.6	(79.1 – 92.1	153	0.207
Other	20.6	(11.5 – 32.7)	13.5	(7.9 – 20.9	29	
Sexually Active						
Yes	90.5	(80.4 – 96.40	93.3	(87.2 – 97.1	168	0.500
No	9.5	(3.6 – 19.6)	6.7	(3.0 – 12.8	14	
No. sexual partners in past year†						
0	7.9	(2.6 – 17.6)	2.5	(0.5 – 7.3)	8	0.191
1	34.9	(23.3 – 48.0)	42.4	(33.3 – 51.8)	72	
2 or more	57.1	(44.1 – 69.5)	55.1	(45.7 – 64.3)	101	
Regular sexual partner†						
Yes	69.8	(57.0 – 80.8)	74.6	(65.7 – 82.1)	132	0.495
No	30.2	(19.2 – 43.0)	25.4	(17.9 – 34.3)	49	
Previous pregnancies†						
0	76.2	(63.8 – 86.0)	72.0	(63.0 – 79.9)	113	0.775
1	14.3	(6.8 – 25.4)	14.4	(8.6 – 22.1)	26	
2 or more	6.4	(1.8 – 15.5)	11.0	(6.0 – 18.1)	15	
Prefer not to say	3.2	(0.4 – 11.0)	2.5	(0.5 – 7.3)	5	
Children†						
0	90.5	(80.4 – 96.4)	85.6	(77.9 – 91.4)	158	0.652
1	3.2	(0.4 – 11.0)	7.6	(3.6 – 14.0)	11	
2 or more	3.2	(0.4 – 11.0)	4.2	(1.4 – 9.6)	3	
Prefer not to say	3.2	(0.4 – 11.0)	2.5	(0.5 – 7.3)	5	
Abortions†						
0	79.4	(67.3 – 88.5)	80.5	(72.2 – 87.2)	145	0.950
1	12.7	(5.7 – 23.5)	11.9	(6.6 – 19.1)	22	
2 or more	4.8	(1.0 – 13.3)	3.4	(0.9 – 8.5)	7	
Prefer not to say	3.2	(0.4 – 11.0)	4.2	(1.4 – 9.6)	7	
UPSI in past year††						
Yes	57.1	(44.1 – 69.5)	59.8	(50.4 – 68.8)	69	0.927
No	39.7	(27.6 – 52.8)	37.6	(28.8 – 47.0)	106	
Unsure	3.2	(0.4 – 11.0)	2.6	(5.3 – 7.3)	5	
Taken EC in past year†						
Yes	39.7	(27.6 – 52.8	55.1	(45.7 – 64.3)	90	0.097
No	60.3	(47.2 – 72.4	44.1	(34.9 – 53.5)	90	
Unsure	0.0	(0.00 – 5.69[a])	0.9	(0.0 – 4.6)	1	
Likelihood that OCPs prescribed will be taken†						
Unlikely	1.6	(0.0 – 8.5)	8.5	(4.1 – 15.0)	11	0.019*
Neutral	1.6	(0.0 – 8.5)	9.3	(4.8 – 16.1)	12	
Likely	96.8	(89.0 – 99.6)	82.2	(74.1 – 88.6)	158	
Likelihood of pregnancy whilst on OCPs†						
Unlikely	90.5	(80.4 – 96.4)	84.8	(77.0 – 90.7)	157	0.492
Neutral	6.4	(1.8 – 15.4)	11.9	(6.6 – 19.1)	18	
Likely	3.2	(0.4 – 11.0)	3.4	(0.9 – 8.5)	6	
Feelings of others towards OCP use†						
Negative	6.4	(1.8 – 15.5)	13.6	(8.0 – 21.1)	20	0.325
Neutral	30.2	(19.2 – 43.0)	29.7	(21.6 – 38.8)	54	
Positive	63.5	(50.4 – 75.3)	56.8	(47.3 – 65.9)	107	
Feelings towards pregnancy†††						
Negative	55.7	(42.5 – 68.5)	57.9	(48.3 – 67.1)	100	0.165
Neutral	34.4	(22.7 – 47.7)	23.7	(16.2 – 32.6)	48	
Positive	9.8	(3.7 – 20.2)	18.4	(11.8 – 26.8)	27	

Confidence interval, CI; Index of Multiple Deprivation, IMD; unprotected sexual intercourse, UPSI; oral contraceptive pills, OCPs

*p value significant <0.05

†1 missing value (online contraception n=63; other services n=118)

††2 missing values (online contraception n=63; other services n=117)

††† 7 missing values (online contraception n=61; other services n=114)

[a]one-sided, 97.5% CI

6.6.2 Background Data for Participants with Outcome Data Available

Table 6-4 Sociodemographic Characteristics for Participants included in the OCP Continuation Analysis Comparing Online Contraception Users to Other Service Users (n=129)

	Online contraception (SH:24) (n=42)		Other services (n=87)			
	%	95% CI	%	95% CI	N	p value (X^2)
Age group (years)						
16 - 19	14.3	(5.4 – 28.5)	24.1	(15.6 – 34.5)	27	0.631
20 – 24	38.1	(23.6 – 54.4)	32.2	(22.6 – 43.1)	44	
25 – 29	28.6	(15.7 – 44.6)	25.3	(16.6 – 35.8)	34	
30+	19.1	(8.6 – 34.1)	18.4	(10.9 – 28.1)	24	
Ethnic group†						
White	57.5	(40.9 – 73.0)	56.6	(45.3 – 67.5)	70	0.976
Black	22.5	(10.8 – 38.5)	21.7	(13.4 – 32.1)	27	
Asian	7.5	(1.6 – 20.4)	8.4	(3.5 – 16.6)	10	
Mixed	10.0	(2.8 – 23.7)	8.4	(3.5 – 16.6)	11	
Other	2.5	(0.1 – 13.2)	4.8	(1.3 – 11.9)	5	
IMD						
1st quintile (most deprived)	47.6	(32.00 – 63.6)	35.6	(25.7 – 46.6)	51	0.425
2nd quintile	33.3	(19.6 – 49.6)	46.0	(35.2 – 57.0)	54	
3rd quintile	16.7	(7.0 – 31.4)	11.5	(5.7 – 20.1)	17	
4th quintile	2.4	(0.1 – 12.6)	5.75	(1.9 – 12.9)	6	
5th quintile (least deprived)	0.0	(0.0 – 8.4††)	1.15	(0.1 – 6.2)	1	
Education†						
Entry Level – Level 2	12.5	(4.2 – 26.8)	8.4	(3.5 – 16.6)	12	0.746
Level 3 - 5	30.0	(16.6 – 46.5)	28.9	(19.5 – 39.9)	36	
Level 6 - 8	57.8	(40.9 – 73.0)	62.7	(51.3 – 73.0)	75	
Employment†						
Employed	52.5	(36.1 – 68.5)	47.0	(35.9 – 58.3)	60	0.906
Student & Employed	7.5	(1.6 – 20.4)	8.4	(3.5 – 16.6)	8	
Student	32.5	(18.6 – 49.1)	38.4	(28.1 – 49.9)	45	
Unemployed	7.5	(1.6 – 20.4)	5.8	(2.0 – 14.0)	10	

Confidence interval, CI; Index of Multiple Deprivation, IMD
† 6 values missing for Education, Ethnic group and Employment (online contraception n=40; other services n=83)
††one-sided, 97.5% CI

The results presented in Table 6-4 show that the lack of statistically significant differences between the two groups in terms of sociodemographic variables was retained when the sample was restricted to only those participants with data available for the outcome variables (n=129).

6.6.3 Continuation of OCPs in the Online Group Compared to the Other Services Group

Table 6-5 presents the proportion of participants obtaining a second prescription of OCPs by service. The proportion continuing OCPs was 59.0% in the online contraception group compared with 39.1% of participants in the other services group with the odds of a second prescription more than doubling for the online contraception group (OR 2.29, 95% CI 1.08 – 4.86, p=0.031).

For the outcome of continuation of any effective method of contraception, a greater proportion of the online group (61.9%) compared to the other services group (46.0%) continued on any effective method, but the risk difference was not statistically significant (15.93%; 95% CI -2.11 – 33.97; p=0.090). Six participants (15.0%) from the other services group switched to other effective methods (10.0% switched to implants; 2.5% switched to IUDs; 2.5% switched to

vaginal rings) which was more than those who switched to another effective method in the online group in which only 1 person out of 26 (3.9%) switched from OCPs to an IUD.

Two secondary outcomes were statistically significantly associated with type of service. Switching to condom-use was not reported by any participants in the online group, compared to 9.2% of the other services group which gave a statistically significant risk difference of -9.20 (-2.11 – -33.97) (p=0.042). Among those who discontinued, the risk of discontinuation due to a late prescription of contraception was greater in the online contraception group (Table 6-5). In the online group, 50.0% of those who discontinued contraception had a late prescription (i.e. participants self-reported continuation, but their service records had a record of attendance for effective contraception beyond 4 weeks of their first prescription expiry) as their reason for discontinuation, whist 23.4% had a late prescription in the other services group giving a risk difference of 26.60% (-0.73 – 53.92) (p=0.045).

Table 6-5 Proportion Continuing OCPs and Further Secondary Outcomes Relating to Continuation and Discontinuation including Risk Differences Comparing Online Contraception Users to Other Service Users (n=129) (n stated within table when proportions for secondary outcomes are from a sub-sample)

	Online contraception (SH:24) (n=42)		Other services (n=87)					
	%	95% CI	%	95% CI	OR (95% CI)	p value	Risk difference (95% CI)	p value
Primary Outcome: OCP continuation								
OCPs continued	59.5	(43.3 – 74.4)	39.1	(28.8 – 50.1)	2.29 (1.08 – 4.86)	0.031*	20.44 (2.10 – 38.48)	0.029*
Secondary Outcomes								
Any effective method continued	61.9	(45.6 – 76.4)	46.0	(35.2 – 57.0)	1.91 (0.90 – 4.05)	0.092	15.93 (-2.11 – 33.97)	0.090
Switch to condoms	0.0	(0.0 – 8.8†)	9.2	(4.1 – 17.3)	--††	--††	- 9.20 (-15.27 - -3.12)	0.042*
Pregnancy risk during study	19.1	(8.6 – 34.1)	32.2	(22.6 – 43.1)	0.50 (0.20 – 1.21)	0.123	-13.14 (-28.54 – 2.27)	0.119
Secondary outcomes for those continuing effective methods (n=66)	Online contraception (SH:24) (n=26)		Other services (n=40)					
Type of effective§ method continued:								
Implant	0.0	(0.0 – 13.2†)	10.0	(2.8 – 23.7)	--††	--††	-10.00 (-19.30 – -7.03)	0.096
IUD	3.9	(0.1 – 19.6)	2.5	(0.1 – 13.2)	1.56 (9.33 – 26.09)	0.610	1.35 (-7.49 – 10.18)	0.755
Vaginal ring	0.0	(0.00 – 13.2†)	2.5	(0.1 – 13.2)	--††	--††	-2.50 (-7.34 – 2.34)	0.417
Remaining at same service for next prescription	84.6	(65.1 – 95.6)	82.5	(67.2 – 92.7)	1.17 (0.30 – 4.46)	0.822	2.12 (-16.08 – 20.31)	0.823
Secondary outcomes for those discontinuing effective methods (n=63)	Online contraception (SH:24) (n=16)		Other services (n=47)					
Reasons for discontinuation of any effective method (n=63)								
Method	6.3	(0.0 – 18.5†)	10.6	(11.5 – 36.0)	0.56 (0.06 – 5.19)	0.610	-4.39 (-19.17 – 10.39)	0.606
Service	25.0	(7.3 – 52.4)	23.4	(12.3 – 38.0)	1.09 (0.29 – 4.07)	0.897	1.60 (-22.83 – 26.02)	0.897
Personal circumstances	12.5	(1.6 – 38.4)	21.3	(10.7 – 35.7)	0.53 (0.10 – 2.72)	0.446	-8.78 (-28.76 - 11.21)	0.440
Pregnancy	6.3	(0.2 – 30.2)	2.1	(0.1 – 11.3)	3.07 (0.18 – 52.09)	0.438	4.12 (-8.44 – 16.68)	0.417
Late repeat prescription†††	50.0	(24.7 – 75.4)	23.4	(12.3 - 38.0)	3.27 (1.00 – 10.76)	0.051	26.60 (-0.73 – 53.92)	0.045*
Unknown	0.0	(0.0 – 20.6†)	6.4	(1.3 – 17.5)	--††	--††	-6.38 (-13.37 – 6.06)	0.300
Action taken in response to pregnancy risk among those reporting a pregnancy risk during study (n=36)	Online contraception (SH:24) (n=8)		Other services (n=28)					
No action taken	50.0	(15.7 – 84.3)	39.3	(21.5 – 59.4)	1.54 (0.32 – 7.50)	0.589	10.71 (-28.37 – 49.80)	0.588
Attended same service	25.0	(3.2 – 65.1)	10.7	(2.3 – 28.2)	2.78 (0.38 – 20.50)	0.316	14.29 (-17.83 – 46.40)	0.303
Attended new service	25.0	(3.2 – 65.1)	10.7	(2.3 – 28.2)	2.78 (0.38 – 20.50)	0.316	14.29 (-17.83 – 46.40)	0.303
Used a leaflet	0.0	(0.0 – 36.9†)	7.1	(0.9 – 23.5)	--††	--††	-7.41 (-16.68 - 2.40)	0.437
Used the internet	0.0	(0.0 – 36.9†)	32.1	(15.9 – 52.4)	--††	--††	-32.14 (-49.44 - -14.84)	0.059

Confidence interval, CI; Index of Multiple Deprivation, IMD; odds ratio, OR

*p value significant <0.05

†one-sided, 97.5% CI

††no observations for online group, exposure predicts outcome perfectly

†††Participants self-reported continuation, but their service records had a record of attendance for effective contraception beyond 4 weeks of their first prescription expiry

§ All methods, including OCPs, with effectiveness >90% according to typical use percentages from the Family Planning Association (FPA) (316)

Most of those who continued their OCPs in both groups (online contraception n=25; other services n=34), accessed their second pack prior to their first pack expiring (52.5%), thus the median number of days from first prescription expiry to accessing the next OCP prescription, shown in Table 6-6, are negative for both the online group (median = -3.00; IQR = -17.00 – 5.00) and the other services group (median = -0.50; IQR = -10.00 – 2.00). There was no statistically significant difference (p=0.508) observed between the mean time in days from first OCP prescription expiry to access to second prescription of OCPs in the online contraception group (mean=-7.12; SD=20.90) versus the other services group (mean=-7.00; SD=24.66) among those accessing a second prescription.

Figure 6-3 shows the cumulative frequency of proportions accessing their OCPs at each week since their first prescription expiry (indicated at week 0 in the graph) among those accessing a second prescription (n=59) within four months of recruitment. The curves for the online group (SH:24) and the other services group follow a similar trend until -5 weeks at which point the SH:24 curve becomes more steep than the other services curve and the distance between the two curves widens, which is indicative of both the greater proportion of online contraception service-users continuing OCPs and the slightly higher proportion accessing OCPs compared to other services during the period from -5 weeks to 4 weeks since first prescription expiry.

Table 6-6 Mean Days between First Prescription Expiry and Second Prescription of OCPs within four Months of First Prescription According to Service-use Data Comparing Online Contraception Users to Other Service Users (n=59)

	Online contraception (SH:24) (n=25)		Other services (n=34)		
Interval between 1st prescription expiry and 2nd prescription	Mean	SD	Mean	SD	p value
	-7.12	20.90	-7.00	24.66	0.508
	Median	IQR	Median	IQR	p value
	-3.00	-17.00 – 5.00	-0.50	-10.00 – 2.00	0.902

Standard deviation, SD; interquartile range, IQR

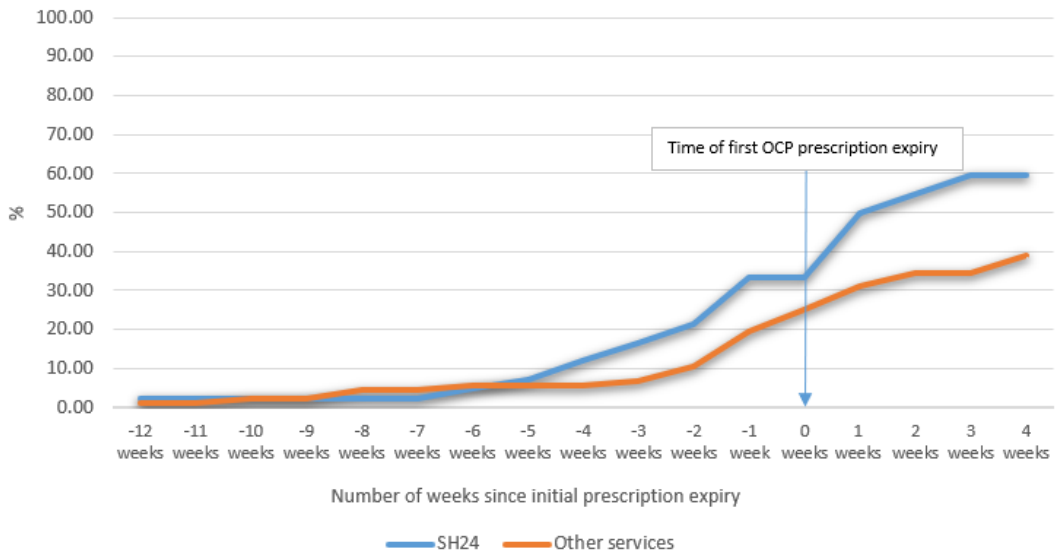


Figure 6-3 Line Graph of Cumulative Proportion Accessing New OCP Prescription at Weeks Since Initial OCP Prescription Expiry (initial prescription expiry shown at 0 weeks)
Oral contraceptive pills, OCPs

6.6.4 Bivariate and Multivariable Analysis of Association Between Type of OCP Service and OCP Continuation

Table 6-7 shows the results of a crude and multivariable logistic regression, to examine whether the association between type of OCP service and OCP continuation is retained after adjustment for covariates. The online contraception exposure was significantly associated with OCP continuation (crudeOR = 2.56, 95% CI 1.18 – 5.57; p=0.018) although with a slightly different OR to that shown in Table 6-5 due to the sample restriction brought about by missing data for the covariates.

Two multivariable analyses were conducted and in both, the positive and statistically significant associations between using the online OCP service and OCP continuation were retained. In the first model, all sociodemographic covariates were included in the analysis (age group, ethnic group, IMD quintile, employment status and education level) in addition to the main exposure of service type. In this model, the OR for OCP continuation for those in the online contraception group compared with the other services group was increased compared to that observed in the crude analysis (adjOR = 3.13, 95% CI 1.28 – 7.65; p=0.012).

The second model adjusted for two additional covariates. The previous analyses in this chapter (see Table 6-3) shows that there were significantly fewer smokers in the online contraception group compared to the other services group (17.5% versus 32.8%; p=0.028). There was also a statistically significant difference (p=0.019) in the Likert scale responses to the likelihood that OCPs prescribed would be taken with 96.8% of the online contraception group responding positively compared to 82.2% of the other services group. Therefore, both these covariates were included in a further multivariable analysis, in addition to the available sociodemographic variables. In this second model, the association between online service and OCP continuation was retained, and increased slightly compared to the bivariate analysis, but was attenuated

relative to the model including sociodemographic covariates only (adjOR = 2.93, 95% CI 1.17 – 7.31; p=0.022).

Table 6-7 Crude and Adjusted ORs of OCP Continuation by Type of Service Used for Initial OCP prescription Comparing Online Contraception Users to Other Service Users (n=121[†])

	Crude OR (95% CI)[a]	p value	Adjusted OR (95% CI)[b]	p value	Adjusted OR (95% CI)[c]	p value
Exposure						
Other services	1 (ref)	-	1 (ref)	-	1 (ref)	
Online contraception	2.56 (1.18 – 5.57)	0.018*	3.13 (1.28 – 7.65)	0.012*	2.93 (1.17 – 7.37)	0.022*

Confidence interval, CI; odds ratio, OR
*p value significant <0.05
[†]Further reduction in sample size from primary outcome data (Table 6-5) due to missing data from self-reported questionnaire at 6 days post recruitment (online contraception n=40; other services n=81)
[a]Adjusted for exposure
[b]Adjusted for exposure; age group; ethnic group; IMD quintile; employment status; education level
[c]Adjusted for exposure; age group; ethnic group; IMD quintile; employment status; education level; smoking status; likelihood that OCPs prescribed will be taken

6.7 Discussion

6.7.1 Key Findings

Those participants who used the online contraception service (SH:24) for their first supply of OCPs were significantly more likely to experience short-term continuation of this method compared to participants using other services (SRH clinics and GPs), and this positive association was retained after controlling for sociodemographic and other characteristics. There was no difference in the timing of access to the next prescription of OCPs between those who continued in the online group compared to those who continued in the other services group. The online service users were also less likely to report having switched to using condoms compared to the users of other services.

6.7.2 Methodological Considerations

Strengths

This was a multi-site cohort study, recruiting service-users from the online service, multiple SRH sites in Lambeth and Southwark and some general practices. By capturing data on OCP service-use from such a range of providers in Lambeth and Southwark, the outcomes of this study are informative of service-users' contraceptive access and decision-making across the landscape of providers in the area. Data sources were both self-reported questionnaires and objective, routinely-collected data from services. Self-reported questionnaires were valuable in capturing background data in areas including motivation to prevent pregnancy, relationship status and reproductive history and importantly, discontinuation and reasons for discontinuation. Objective data was essential to determine eligibility, and then to confirm the primary outcomes of continuation and time from first OCP expiry and access to second OCP supply.

As the study was observational, the results provide insight into the differences between those choosing to access their first OCP supply from SH:24 during its first year of availability and those accessing their first supply from other services. These results are therefore important in understanding how the target population have responded to the introduction of online contraception into the existing landscape of providers.

Limitations

The fundamental limitation of this study is that, due to low recruitment, the sample size available for analysis was below the target set by the sample size calculation. Although there was a significantly greater proportion continuing OCPs in the online group compared to the other services group, the result lacked precision, with large confidence intervals around the risk difference (20.44%, 95% CI 2.10 – 38.48). This low level of precision impacts how the results can be interpreted in terms of their clinical importance when considering the extent to which online services can improve short-term contraceptive continuation.

Several of the secondary outcomes demonstrated indications of differences between the online and other services groups but were underpowered for statistically significant findings. For the secondary outcome looking at the difference in the mean number of days from the first supply of OCPs finishing and the acquisition of a new pack, there were only 59 observations available (online services n=25; other services n=34). This provided only 5% power to detect a difference of 0.5 between the means, based on a two-sided t-test with a 5% significance level. The sample size available for the logistic regression analyses in Table 6-7, was further reduced due to missing data for some of the covariates included in the multivariable analyses (n=121). Caution is needed when interpreting findings where sub-category numbers are very small, for example, by ethnic group.

Recruitment for this study is currently ongoing, therefore it is recommended that the findings presented in this chapter are taken as provisional results until the analysis can be repeated on the final sample (scheduled for mid-2019). It was not possible to await the completion of recruitment due to the time constraints of the thesis. As mentioned in section 2.10, the original plans for this thesis were centred on online EC provision which the SH:24 service had to postpone indefinitely due to changing commissioning priorities. Thus, fifteen months into the start of the PhD process, new study protocols had to be written, ethical approval gained, and revised plans implemented, leaving reduced time for conducting the research. Furthermore, recruitment was slower than had been anticipated. It was therefore decided to extract the data from participants who had been recruited prior to the end of 2017 so that follow-up procedures could be completed and to enable sufficient time for analysis and write-up prior to the thesis submission deadline.

There were several reasons for recruitment rates being poorer than anticipated which differed according to the study site. Recruitment in community clinics began in October 2016, but because the launch of the online service was delayed, recruitment from the intervention could

not begin until January 2017. During this very early period of online contraception availability, uptake among the target population was limited so recruitment for this exposure group was slow and sporadic until approximately March 2017. It also took some time to refine the recruitment process as there was no precedent in the literature for recruiting participants entirely remotely from this type of online platform, via links to a study website. The recruitment procedure for the online group was largely automated, which was beneficial in terms of resource allocation, but may have had a negative impact where potential participants did not sign up.

More personalised, direct recruitment by researchers positioned in clinics was a comparatively successful strategy for recruitment in the other services group. However, this was a resource intensive endeavour and inconsistently applied as it depended on the availability of researchers and of rooms in clinics for private communication with prospective participants. It was also highly dependent on referrals from non-research staff within sites, which varied according to the extent that they felt motivated, encouraged, well-informed and able to prioritise this among their competing tasks. Recruitment was largely unsuccessful in general practices as it was not possible to position researchers within these sites and staff not directly related to the research did not prioritise referrals to the study. In order to expand recruitment beyond the larger community clinics to include a range of services available to Lambeth and Southwark residents, online recruitment via social media sites, Facebook and Instagram was temporarily utilised. However, this strategy was problematic due to the narrow eligibility criteria. Those that did sign up needed to have their eligibility verified at the service they named for their first OCP prescription and several had to be removed from the study due to missing data, no record of attendance or failure to meet all stated eligibility criteria when records were checked. A disproportionate representation of attendees from community clinics relative to general practice attendees is unlikely to reflect the contraceptive service-use in Lambeth and Southwark as we know that the majority of UK women aged 16 – 44 years (59.1%) access their contraception from their GPs (70). Recruitment from more general practices and local Brook services (free sexual health services to people aged under 25 years) was attempted, through emails, phone calls, visits to services, meetings with staff and a posting in the Lambeth CCG GP bulletin (317), but was largely unsuccessful. Thus, the services included in the study did not reflect the range of services available in Lambeth and Southwark, including Brook services which provide SRH services to those aged under 25 years.

Recruitment procedures may also have influenced the extent to which the results reflect the characteristics of OCP users and the likelihood of short-term continuation in the general population with participants of the study potentially having a heightened interest in contraceptive service research or other unknown characteristics. Participants were given £5 cash upon completion of the first questionnaire and £10 upon completion of the second which may have introduced a bias in uptake of the study and the completion of questionnaires towards those with a particular interest in acquiring the incentive, however, this should have been non-differential between exposure groups.

Unlike Chapter 5, the CiP-CO study had questionnaire data sources so collected more data on sociodemographic background information with variables on education level and employment status of the individual in addition to IMD quintile of area of residence, age and ethnicity. However, this information could still be considered limited in terms of capturing all relevant information in this domain. IMD as a measure of deprivation relates only to the area in which the service-user lives, rather than to the status of the individual. Other contraceptive studies, such as those using NATSAL data, have also considered job role and income level for better understanding of individual socioeconomic status (SES) (151). However, it was also important that the questionnaires struck a balance between comprehensive collection of data and speed of completion in order to minimise participants becoming fatigued or abandoning them prematurely.

Further limitations of the study were that with three self-reported data collection points (Figure 6-1), there were two points of attrition, reflected in the poor follow-up rates. The use of objective data for the primary outcome reduced the impact of this, however, there were issues with discrepancies between objective and self-reported data, both in terms of claims of eligibility for the study, and where participants had stated that they had continued effective contraception, but this was contradicted according to service records. In addition, there were 8 participants who stated they had continued, but the provider did not respond to requests for objective data. It was also not possible to obtain objective data from non-NHS, private services and from most pharmacies. Communication with participants when encouraging follow-up over the phone, suggested that not all participants had clarity around the purpose of the study. Some felt that because they did not take any or all of their first OCP prescription, that their data was no longer of value so they should not take part and complete the other questionnaires. The definition of "discontinuation" employed by the study may not have corresponded with participants' understanding of discontinuation. Those who obtained OCPs outside of the month after their first OCP prescription could have completed their questionnaire late or could have stated they were continuing despite not yet having attended the service.

This was an observational study, so it is important to reflect on the extent to which the continuation outcomes are the result of variables unrelated to the nature of the exposure. The sample selection may also have increased the potential for confounding with participants likely to have particular characteristics that made them inclined to take part in research, limiting the extent to which the results can be indicative of the contraceptive decision-making in the general population of either community clinic and general practice attendees or online contraceptive users.

6.7.3 Findings in Relation to Other Studies

Chapter 2 emphasised the dearth of literature on the impact of free-to-access, online contraceptive services. However, there are studies which consider self-reported factors involved

in the decision-making around contraceptive continuation more broadly which provide encouraging support for the results found in this chapter.

The results of this study suggest that the type and quality of service are important in determining contraceptive decision-making with users of online contraception more likely to continue their OCPs than users of other services, namely community clinics and general practice. US studies have associated discontinuation with access issues within free-to-access contraceptive services (79, 307). Westhoff et al. (2007) found that participants who were initiating OCPs at publicly funded providers self-reported that access was their main reason for discontinuation, which included running out of pills, being unable to get back to the clinic, forgetting to take the pill and similar problems that were related to either obtaining the pill or using it correctly (79). Other studies have found that access issues are less relevant than perceptions and experiences of side-effects (75, 306, 318), whilst a study by Moreau et al. (2007) defined reasons for discontinuation very broadly as being due to "dissatisfaction" with the method, finding that 46% of the 6724 women surveyed had discontinued at least one method for this reason (319). The reasons for discontinuation reported here also use broad categories such as "service" and "method" to encompass self-reported data for those participants who did not continue with an effective method of contraception according to objective data (Table 6-5). The difficultly with this type of reporting is that reasons for discontinuation are not easily delineated. Participants discontinuing due to side-effects could be closely linked with issues with the service; potentially reflecting limitations in the quality of the contraceptive counselling provided to adequately advise contraceptive users about side-effects. UK clinical guidelines contain the advice that "women should be informed thoroughly about all potential side effects when starting contraception" in addition to information about non-contraceptive health benefits and risks associated with use (83). The group who used the online contraception service for their first prescription of OCPs were more likely to continue to their second prescription, which may suggest that the various elements of the online service were effective in minimising access issues, side-effect concerns and other types of dissatisfaction that are typical obstacles to continuation.

In the process of conducting the crude and adjusted logistic regression analyses in this chapter, the individual associations between each covariate and the outcome of OCP continuation were also examined (this was considered beyond the scope of the focus of this chapter but can be found in Appendix G). Briefly, these analyses indicated that those of black ethnic group had significantly lower odds of OCP continuation (crude OR 0.34; 95% CI 0.12 – 0.93; p=0.036), and this association was retained in the multivariable analysis. There were too few numbers available for sub-group analyses for any conclusive interpretation of these findings. Nonetheless, when considered in the light of the literature in this area, it is clear that there is a need for further investigation of the likelihood of OCP continuation according to ethnic group and the extent to which type of OCP service could affect this association. Sexually active women from minority ethnic groups are less likely than white women to use effective methods of contraception (8) and a study on OCP continuation within a 12-month follow up period found

that black women were more likely to discontinue than women in other ethnic groups (adjusted hazard ratio [HR] 1.21, 95% CI 1.02 – 1.44) (307).

6.7.4 Findings in Relation to Conceptual Model and Theoretical Framework

The findings in this study provide some support for the proximal outcome in the ToC conceptual model (Figure 4-2) that depicts improved contraceptive continuation as a proximal outcome of online contraception. Furthermore, by conducting analyses that accounts for multiple background variables, the study attempts to address the assumptions raised by stakeholders in Chapter 4; that positive effects of the online service would vary according to the perceptions and circumstances of potential service-users. Very few of the background variables captured were significantly different between groups, however, the online group had more people reporting that they were likely to use the OCPs prescribed, indicating that the online service group had greater motivations to adhere to OCP use. This is reflective of the qualitative results in Chapter 4 in which potential users of online contraception were considered to have heightened autonomy and to be likely to "know what they want". Owing to the limitations of the study highlighted in section 6.7.2, there may be more profound differences between online service-users and those accessing face-to-face providers that were not detected, even with the use of detailed questionnaires.

This also links to Bourdieu's concept of habitus, described in Chapter 3 as the acquired system of dispositions that reflect past experiences, traditions and habits that generate and organise how people act and think in accordance with the social context (230, 231). The CiP-CO questionnaire may have recognised subtle differences between the online and other services group that could be indicative of habitus. For example, the online group had a smaller proportion reporting use of EC in the past year and a significantly smaller proportion of smokers compared to the other services group, suggesting that the online service could attract those of a more risk averse habitus, which could be linked to effective contraceptive practice to avoid the risk of unplanned pregnancy.

There was also a statistically significant difference in the proportion of online users who stated in their first questionnaire that they were likely to take the OCPs prescribed. It is interesting that a greater proportion of service-users would acquire a prescription of OCPs from a community clinic or GP with minimal intentions to take them. This may be indicative of the patient-provider power dynamic within clinic environments, in which there may be conflict in terms of what both parties are seeking to achieve within the consultation. A patient attending a service for non-contraceptive needs, such as STI-testing, may not wish to take contraception, despite being at risk for unplanned pregnancy; the provider, with increased capital and power in the field, may be able to elicit uptake of OCPs, but may not be able to impact routinised contraceptive practice once the patient has left the consultation. Conversely, online contraception may be sought out by those with greater agency in their acquisition of OCPs and motivation to comply and continue with the method in their daily practice. It is also interesting that the proportion discontinuing

contraception due to “personal circumstances” is substantially smaller in the online group (12.5%) compared to the other services group (21.3%) although not with a statistically significant risk difference (p = 0.440) (Table 6-5), which could be related to the initial lack of motivation to use the OCPs among some of the “other service” users. These findings suggest that the accumulation of capital and the unifying and reinforcing power of habitus are dynamic and active components of practice and involve processes and social interactions that take place beyond the field of the patient-provider consultation. Thus, positive findings in the online group are likely to reflect their motivations, borne of the habitus and capital which stimulated their access of OCPs, in addition to the quality and nature of the online service and its interactions with the participants.

6.7.5 Implications

To my knowledge, this is the first study to compare outcomes relating to contraceptive continuation between participants accessing a free, NHS commissioned, online contraception service and those accessing GPs and SRH services for their 3 months’ supply of OCPs. Despite the problem of under-recruitment and the study being underpowered for its primary outcome, the difference between OCP continuation in both groups was of a sufficient magnitude for a statistically significant result to be detected. Moreover, the online contraception group had significantly greater odds of OCP continuation at the bivariate and multivariable level. This provides the first indication that the public health impact of online contraception could be to improve short-term OCP continuation.

Among those who continued to their second OCP prescription, there was no difference in the timing of access to the next prescription between those in the online group compared to those in the other services group. Most of those who continued their OCPs in both groups (online contraception n=25; other services n=34), accessed their second pack prior to their first pack expiring (52.5%). This suggests that those who continued their OCPs were conscientious of their contraceptive coverage, regardless of the service they used. However, it is necessary to be cautious in the interpretation of this finding, as so few participants continued to their second pack of OCPs. Other studies considering timing and continuation are limited to those looking at month of discontinuation over 12 months comparing different short-acting methods (307) and studies analysing changes to pill regimen (320). More conclusive evidence about the effect of service-type is likely to come from an expanded sample size for this study.

In the comparison of background covariates between exposure groups, only self-reported smoking status and the predicted likelihood that the OCPs prescribed at recruitment would be taken were significantly different according to service type. Fewer participants reported smoking in the online group, which could be indicative of more risk-averse attitudes to health in those accessing SH:24 for online contraception compared to other services and could be consequential in the light of the positive association between smoking and unplanned pregnancy found in the analysis of NATSAL-3 data (1). Participants were more likely to respond

positively to their likelihood of taking the OCPs in the online group which also suggests that the online service may attract those more motivated to use this form of contraception, possibly because in clinics and GPs, participants may be attending for other, non-contraceptive reasons and have accessed OCP incidentally rather than purposefully, perhaps due to encouragement from their providers (321). Inclusion of these covariates in addition to sociodemographic variables in the second multivariable model testing the association between type of service and OCP continuation, did increase the odds of continuation in the online group. Although the association between either smoking status or likelihood of taking the OCP and OCP continuation was not statistically significant in the bivariate or multivariable models, it is unclear the extent to which these covariates impacted the association between type of service and continuation relative to other variables included in the model (additional results shown in Appendix G).

6.7.6 Directions for Future Research

It was discussed in section 2.9.1 that the black ethnic population is substantial in Lambeth and Southwark, relative to other boroughs in London and the UK. Therefore, in this context there is an urgent need for further research into the barriers to continuation that could be affecting black and other BAME women. Again, a larger sample size for this study would also help to make results more conclusive and could potentially detect if there are differences within the smaller sub-categories of ethnicity, such as differences in outcomes between the black Caribbean and black African groups.

As an observational study, the findings are likely to be affected by residual confounding. Therefore, an RCT is recommended to randomly allocate OCP users to either the online or other services exposures, thus minimising the potential for confounding. This would test the hypothesis that there is a causal relationship between the online contraceptive service and the outcome of OCP continuation. Such a design would also benefit from examining longer-term outcomes, such as contraceptive continuation at 6 months and 1 year, and, should the sample size be large enough, the outcome of unplanned pregnancy.

Despite the combination of self-reported and objective data sources as befitting the paradigm advocated by Bourdieu of reflexive sociology, the study remains rather limited in its appreciation of subjective perceptions of online contraception. Further qualitative research is required to understand more of the complex motivations and decision-making that are borne of the habitus and that influence people's contraceptive practice in this new field of contraceptive service delivery.

Another potential determinant of the contraceptive practices highlighted in this study is the distribution of capital. One type of cultural capital that is relevant in the field of contraception is the knowledge of how to safely and effectively use OCPs. The next chapter will look at differences in basic OCP knowledge between the online and other services group. It will also

examine differences in service feedback rating outcomes which will help to indicate what may have been the active components that have led to improved continuation among those using online contraception. It will also provide the basis for a process evaluation to reveal the factors that are contributing to the quality of the service and how it could be further developed and improved.

6.8 Summary of Chapter 6

- Those participants who used the online contraception service for their first supply of OCPs were significantly more likely to experience short-term continuation of this method compared to participants using other services, and this statistically significant association was retained after adjustment for sociodemographic and other variables.
- There was no difference in the number of days from first OCP prescription expiry to access to the next prescription of OCPs among those who continued this method between exposure groups.
- Participants in the online contraception group were less likely to be smokers and more likely to respond positively to the question of whether they were likely to take their OCPs when compared to those using other services.
- This study has provided evidence in support of the prediction that online contraception could improve short-term continuation of OCPs and highlights the need for further research among a larger study population.

7 The Contraception in Person - Contraception Online (CiP-CO) Study: Process Evaluation

7.1 Chapter Overview

This is the second part of the CiP-CO cohort study presented in Chapter 6. The previous chapter focused on how the CiP-CO results were informative about the potential public health impact of online contraception with the key result being that those participants who used the online contraception service for their first supply of OCPs were significantly more likely to experience short-term continuation of this method compared to participants using other services. This chapter takes a process evaluation approach, considering the nascent online contraception service in terms of service-user feedback and basic knowledge of OCPs, comparing outcomes to participants using other services for their first supply of OCPs.

7.2 Background and Rationale

The ToC model resulting from the qualitative study in Chapter 4 (Figure 4-2) conceptualised the positive processes of change from the input of online contraception in this target population to the ultimate outcome of a reduction in rates of unplanned pregnancies. There were three key assumptions about how the target population would respond to online contraception, which related to perceptions of convenience and anonymity of the home delivery process, trust in service-users' capabilities to effectively use contraception facilitated by the online consultation process and website information pages; and the degree to which service-users would prefer remote interaction with their provider.

Understanding the impact of the online service on knowledge is of value because OCP-users are at risk of unplanned pregnancy if they fail to comply with pill-taking guidance (83, 87). In addition, erroneous beliefs regarding the probable side-effects of contraception can lead to OCP discontinuation. Perceptions of side effects are often cited as key contributors to women's decisions about OCP discontinuation and inconsistent use (79-81). Guidelines contain the advice that "women should be informed thoroughly about all potential side effects when starting contraception" in addition to information about non-contraceptive health benefits and risks associated with use (83).

Understanding participants' perceptions of their service-use experience is also of value to indicate what elements of the intervention may have contributed to the findings presented in Chapter 6; namely, that participants who used the online contraception service for their first supply of OCPs were significantly more likely to experience short-term continuation of this method compared to participants using other services. Measures of quality were privacy, convenience, communication, speed, information and choice and were selected on the basis of results of the ToC study in Chapter 4, in addition to findings from the literature. People

accessing services for sexual and reproductive health can feel heightened sensitivity about their privacy, particularly adolescents (259, 322, 323) and SRH services have been reported as being inconvenient to attend (322). Communication is an important area of quality because satisfaction with OCPs is associated with users being satisfied with their relationship with their provider (324). Choice is a marker of quality in contraceptive services because of women's more pronounced preference to exercise autonomy in their contraceptive choices compared to other health concerns (247). Studies have also shown that being well-informed through educational interventions can increase knowledge about contraception which could relate to more effective and confident contraceptive decision-making (325).

Therefore, this study considers how measures of OCP knowledge and service feedback are associated with type of contraceptive service access (online or face-to-face) among a population of OCP users during the first 15 months of the online service being available to residents of Lambeth and Southwark. The results pertaining to OCP knowledge provide measures of the capabilities of service-users to safely and effectively use contraception. The results pertaining to service feedback provide measures of the degree to which service-users rated their OCP services on a range of areas relating to convenience, anonymity and responsiveness of the provider to queries.

7.3 Aims and Objectives

This chapter aims to examine whether measures of OCP knowledge and service feedback are associated with type of contraceptive service access among a population of new OCP users. This study fulfils the following objectives:

- To describe the OCP knowledge of the participants after their first OCP consultation.
- To describe participants' experiences with accessing a service for contraception using rating scores and thematic analysis of free-text responses about services in the area.

7.4 Research Questions

There were conflicting predictions about how the target population would respond to online contraception in terms of knowledge and which areas of quality would score highly relative to GPs and community clinics with face-to-face consultations. The ToC findings acknowledged that perceptions of the online service such as convenience and anonymity would likely be dependent on the circumstances and characteristics of those within the target population who would take up the new service. Therefore, this element of the study is very much exploratory as the first of its kind to consider these outcomes for a service of this nature. The following research questions are considered:

1) Will there be a difference in contraceptive pill knowledge after their first OCP consultation between those accessing from an online service compared to those accessing from other services?
2) What will be the areas of quality in which online services score poorly or highly?

3) Will there be a difference in service rating scores when comparing responses from those using the online service with those using other services for their first supply of OCPs?
4) What do people think about contraceptive services in Lambeth and Southwark?

7.5 Methods

The results presented in this chapter are outcomes of the same study presented in Chapter 6, therefore the main methodological processes were identical and can be read in full in the previous chapter. Where necessary, some additional information specifically pertaining to the methods for the outcomes below, have been included in this chapter.

7.5.1 Outcomes

These secondary outcomes of the CiP-CO study were measured using self-reported data collected via an online questionnaire. The time point of measurement was at 6 days post-recruitment. In addition, free text responses from the CiP-CO study questionnaire sent to participants at 4 months post-recruitment have been used for further qualitative assessment.

Outcomes:

1. Mean contraceptive knowledge scores.
2. % participants providing a correct answer to each question on safe and effective use of OCPs.
3. Self-reported rating scores of experiences of accessing contraception.
4. Self-reported, free-text comments about contraception services in Lambeth and Southwark.

7.5.2 Outcome Variables

Participants are described according to the variables listed in section 6.5.8 and details of the exposure variable can be found in section 6.5.10. This chapter will focus only on the outcome variables relevant to the aims and objectives stated in section 7.3.

Service rating scores: Participants were asked to rate the service they used for their prescription of OCPs accessed at recruitment using a Likert scale response system across 6 areas of service quality and the proportion selecting each point in the scale were recorded categorically. The categorical responses were given numerical scores and totalled for analysis as continuous data.

Service feedback: Participants had the option to provide additional, free-text responses if they felt they had anything further to add regarding contraceptive services in Lambeth and Southwark.

Knowledge scores: Participants answered a series of multiple choice questions relating to safe and effective use of either COC or POP, depending on their self-reported response to the type

of OCP they had just accessed. Most questions had just one correct answer, but some had an "ideal" answer and an "acceptable" answer. This was initially analysed as a binary variable with all ideal and acceptable answers considered correct and all other responses considered incorrect. It was then analysed as a continuous variable using a scoring system. Ideal answers were given the highest score of 2; acceptable answers were given one point less than the ideal answer and all other answers given a score of zero. Correct responses to questions with only one possible correct answer were given the highest score of 2. The total scores were determined for the POP questions and the COC questions, according to exposure.

7.5.3 Data Sources

The data source for the service rating and knowledge outcomes was the self-reported questionnaire delivered at 6 days post-recruitment referred to as Questionnaire One (Appendix E). The free-text responses to the request for further service feedback were collected in the final self-reported questionnaire sent at 4 months post-recruitment (Appendix F). As per the previous chapter, participants were excluded prior to analysis should the objective data not meet the stated inclusion criteria in section 6.5.6. Further information on questionnaire development and delivery is in section 6.5.3.

1) Service Rating Questions from Questionnaire One

The service rating questions were determined firstly, through literature searches to ascertain factors that have been associated with unplanned pregnancy and effective contraceptive use (Chapter 2) and secondly, on the results of the theory of change study which predicted the essential elements of the intervention that would lead to positive processes of change in the target population (Chapter 4). Participants were asked to respond to statements which were designed to collect feedback across 6 domains:

1) Privacy: *I did not have enough privacy when using this service*.

2) Convenience: *It was convenient to access the pill from this service.*

3) Communication: *It would be easy to ask questions or communicate with the service if I had any problems with my contraception over the next three months.*

4) Speed: *Getting oral contraceptive pills from this service was too slow.*

5) Information delivery: *I received all the information about contraception that I needed from this service.*

6) Choice: *This service limited my contraceptive choices.*

Half of the statements were directed negatively and half positively in order to limit acquiescence and response set behaviours (326).

2) Knowledge Questions from Questionnaire One

The rationale for the inclusion and wording of knowledge questions is summarised in Table 7-1. The process involved consideration of FSRH guidelines on OCP prescribing (83, 87),

leaflets for OCP users produced by the Family Planning Association (FPA) (100, 101) and literature on contraceptive knowledge (325, 327-331). After answering all the relevant knowledge questions, participants were shown the correct answers to the questions. Where possible, questions were based on those already in the literature, with some tailoring to ensure they would suit the exposures and outcomes relevant to the study. Details of this are presented in Table 7-1. Pilot questionnaires were tested with clinicians responsible for OCP prescribing in CSHC in addition to one GP practising in Lambeth with a request that particular attention be paid to the knowledge questions to check clinical relevance and accuracy.

Table 7-1 Knowledge Questions in Questionnaire One of the CiP-CO Study and Their Corresponding Evidence-Base

Questions	Guidelines	Literature
You should see a doctor straight away if you experience which of the following side effects? † **- Breathlessness** **- Painful swelling in your leg(s)** **- Pain in the chest** ***- All of the above***	Family Planning Association (FPA) advises that these symptoms (in addition to seven others) warrant immediate contact with a doctor (100) Faculty of Sexual & Reproductive Healthcare (FSRH) have released statements relating to these symptoms of venous thromboembolism (VTE) (332, 333)	VTE risk is increased compared to non-users of combined hormonal contraception (CHC) (334) - adapted from a question in the Contraceptive Utilities, Intention, and Knowledge Scale (CUIKS) (313)
What effect will taking the pill have on your ability to have children in the future? **- Your fertility will increase** **- Your fertility will decrease** ***- There will be no effect*** **- The effect will depend on your age**	FPA advises that "when you stop using the pill your fertility will return to normal" (100)	Women cite the impact on long-term infertility as a reason for lack of uptake and discontinuation of OCPs (335), despite evidence that states that fertility returns to normal following discontinuation(336). Adapted from a question in a 2004 survey to test the effect of counselling on myths (331)
How might your bleeding patterns change when you start taking the pill? †† **- Bleeding may become irregular** **- Being may become lighter or stop altogether** **- Bleeding may last longer** ***- It could be any of the above***	Guidelines stress the importance of providing advice about altered bleeding patterns (87) to reduce discontinuation (88)	Altered bleeding patterns which is a commonly cited reason for discontinuing POPs (84-86)
What effect will taking the pill have on your weight? **- The pill will make your weight go up** **- The pill will make your weight go down** ***- The pill will have no effect on your weight*** **- The effect will depend on your body weight and height**	FPA advice states, "research hasn't shown that the pill causes weight gain. You may find that your weight changes throughout your cycle due to fluid retention" (100) FSRH statement stating that there is no evidence to suggest a causal association between COC/POP use and weight gain (337)	Cochrane review has found no causal association between weight gain and POP use, although available evidence limited and of low quality (338) Cochrane review on hormonal contraceptives for contraception in overweight or obese women, including five COC studies, similarly found no causal association to weight gain (339)
Please read the following scenario then answer two questions about it/the question about it: **SCENARIO 1: Carla went on holiday and missed 4 pills from her packet. When she came back she started taking her pills again as normal. She did not have sex while she was away but she is likely to have sex with her boyfriend now that she is back.**		
For how long will she need to use an additional form of contraception such as condoms to prevent getting pregnant? **- 2 days** **- 5 days** ***- 7 days*** **- She should seek advice from a health service**	FPA advice includes an easy to interpret algorithm of action in the event of missed COCs (100) and bullet point guidance on missing POPs (101) Missed pill advice also provided by NICE (340) based on FSRH guidance (83)	Women can have difficulty in interpreting missed pill instructions, particularly after missing multiple OCPs (341) Missing pills has been linked to unplanned pregnancies (75)
There were only four more pills in her packet when she got back,	Advice on the approach to the 7 day break when pills missed are	Women can have difficulty in interpreting missed pill instructions,

Questions	Guidelines	Literature
what should she do about her 7 day break?† **- She should have her 7 days break as normal** ***- She should skip the break and start her new pill packet*** **- She should seek advice from a health service** **- She should stop taking the pill**	provided by NICE (340) based on FSRH guidance (83)	particularly after missing multiple OCPs (341). Missing pills has been linked to unplanned pregnancies (75).
Please read the following scenario then answer the question about it: **SCENARIO 2: Bernadette went on holiday with Carla and missed 3 pills from her packet. She also had unprotected sex the night before she returned home.**		
Bernadette got back today, what should she do now? ***- She should get emergency contraception*** **- She should not worry because her previous pill use will have protected her from pregnancy during this time** **- She should take a pregnancy test right away** **- She should wait and see if she has a period or not**	FPA advice includes an easy to interpret algorithm of action in the event of missed COCs (100) and bullet point guidance on missing POPs (101)	Women do not always recognise the risk posed by failures in the contraceptive use which can be a barrier to accessing EC when required (132)
Please read the following scenario then answer the question about it: **SCENARIO 3: Anna felt sick this morning and vomited once, half an hour after taking her pill.**		
Anne feels better in the afternoon and doesn't think she will vomit again. What should she do? **- Continue to take the pill as normal** ***- Take another pill immediately then continue as normal*** **- Stop taking her pill and re-start after her next period** **- She should seek advice from a health service**	FPA advice states, "if you vomit within two hours of taking the POP, it won't have been absorbed by your body. Take another pill as soon as you feel well enough" (100)	Missing pills has been linked to unintended pregnancies (75).

† Questions for self-reported COC users only
†† Question for self-reported POP users only
All underlined responses are correct, those that are both underlined and in italics are considered ideal responses whilst those that are underlined only are considered acceptable responses

1) Service Feedback Questions from Questionnaire Two

In the final section of the second questionnaire sent at four months post recruitment, participants had the option of providing a free text response to the statement: "please provide any additional comments about contraception services in Lambeth and Southwark".

7.5.4 Analysis

1) Descriptive statistics were determined for those participants with data available for the outcomes in the study. Tests for significant differences in proportions between the exposure groups for descriptive measures were tested for at a 5% significance level.
2) Questionnaire responses to service feedback questions were assigned numerical codes that would enable univariate analysis using descriptive statistics. Likert scales were combined into indexes for parametric analysis. There was a combination of both positive and negative statements, so numerical codes corresponded with the extent to which the service was viewed favourably, i.e. strongly agreeing with a positive

statement converted to a numerical score of five whilst strongly agreeing with a negative statement converted to one.

3) Questionnaire responses to knowledge questions were analysed categorically according to the proportion correctly answered by exposure. Scores were combined for parametric analysis.
4) Free text responses were thematically analysed using a largely deductive approach to code data according to the themes of service quality generated by the ToC study (Chapter 4) and the service feedback section of the questionnaire. Despite the deductive approach, care was taken to account for any emergent themes. The purpose of the analysis was to provide a descriptive account of the data using the three key steps of detection, categorisation and classification (299). Detection involved looking at the data according to each theme of service quality, noting the various perceptions and views present. These were then sorted into slightly more refined categories relating to the nature and implications of the views under each theme. Classification followed this to consider these themes more conceptually, although not to a high degree of abstraction due to the limited nature of the data which was collected as an additional, less focal element of the survey.

All quantitative analyses were conducted with the use of STATA V.14.1 (StataCorp) and the free text responses were analysed qualitatively using NVivo 11 Pro (NVivo; QSR International Pty Ltd. Version 11, 2018).

7.5.5 Ethical Considerations

Ethical approval for this research was granted by Dulwich Research Ethics Committee (reference: 16/LO/1025). See section 6.5.13 for further details.

7.6 Results

In total, 227 participants were recruited, 77 (33.9%) of whom were subject to the exposure of the intervention of online contraception and 150 (66.1%) who were subject to the exposure of other contraceptive services. All 227 were verified as having attended a contraceptive service for a 3 months' supply of OCPs within 4 weeks of being recruited to the study. Out of this 227, 182 (80.1%) went on to complete or partially complete their first questionnaire at 6 days post-recruitment. Not all elements of the questionnaire were answered fully, hence the further loss to follow-up for service rating scores and knowledge scores (Figure 7-1).

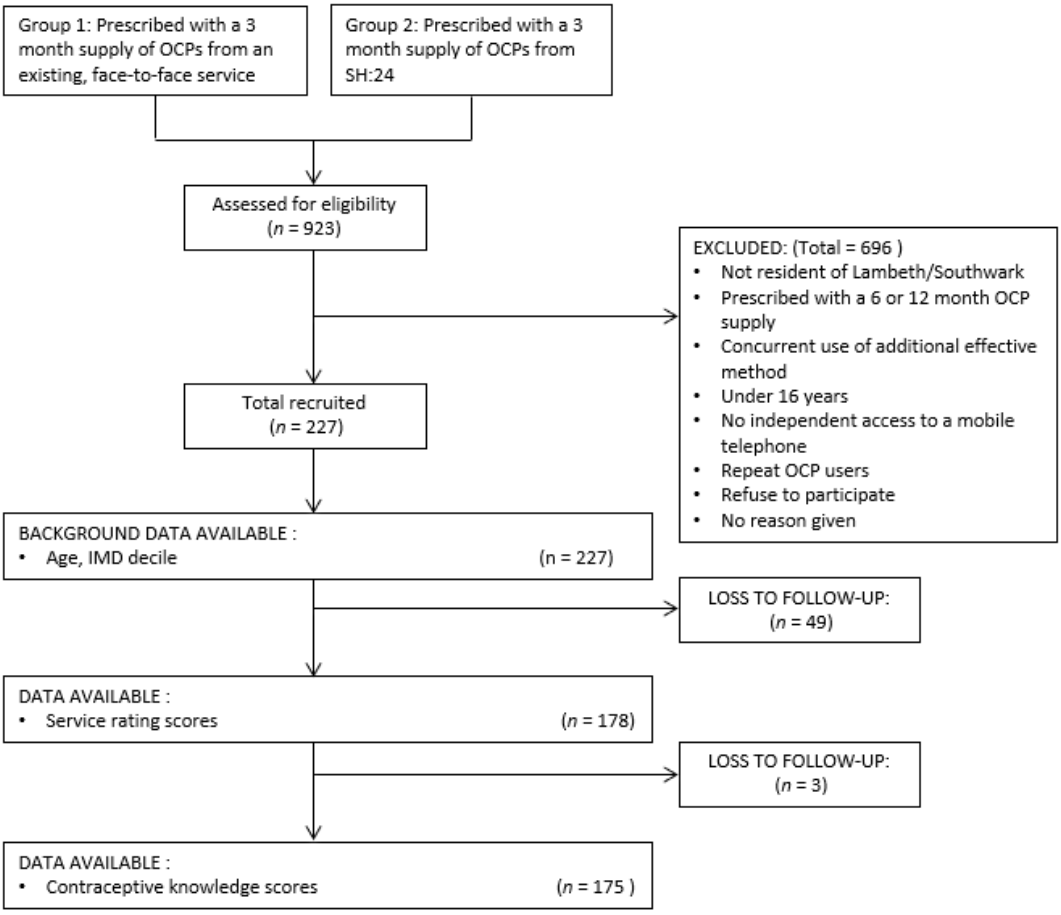


Figure 7-1 Study Flow Diagram
Oral contraceptive pills, OCPs; Index of Multiple Deprivation, IMD

7.6.1 Sociodemographic Data

Sociodemographic data for the 178 participants with data available for service rating outcomes are provided in Table 7-2. There were no significant differences in characteristics between the online contraception (n=62) and other services group (n=116). Three participants out of this 178 did not complete their knowledge questions, 1 from the online contraception group (n=61) and 2 from the other services group (n=114). Chi-squared tests were re-run for this slightly reduced sample and once again, no significant differences in sociodemographic variables were found between the two service groups (age group p value=0.276; ethnic group p value=0.662; IMD decile p value=0.233; education p value=0.706; employment status p value=0.438).

Table 7-2 Sociodemographic Characteristics for Participants included in Analysis for Service Rating Outcomes Comparing the Online Contraception Group to the Other Services Group (n=178)

	Online contraception (SH:24) (n=62)		Other services (n=116)			
	%	95% CI	%	95% CI	N	p value (X^2)
Age group (years)						
16 - 19	9.7	(3.6 – 19.9)	21.6	(14.5 – 30.2)	31	0.206
20 – 24	43.6	(31.0 – 56.7)	36.2	(27.5 – 45.7)	69	
25 – 29	30.7	(19.6 – 43.7)	24.1	(16.7 – 33.0)	47	
30+	16.1	(8.0 – 27.7)	18.1	(11.6 – 26.3)	31	
Ethnic group						
White	61.3	(48.2 – 73.4)	51.7	(42.3 – 61.1)	98	0.668
Black	21.0	(11.7 – 33.2)	23.3	(15.9 – 32.0)	40	
Asian	6.5	(1.8 – 15.7)	7.8	(33.6 – 14.2)	13	
Mixed	9.7	(3.6 – 19.9)	12.1	(6.8 – 19.4)	20	
Other	1.6	(0.0 – 8.7)	5.2	(1.9 – 10.9)	7	
IMD						
1st quintile (most deprived)	43.6	(31.0 – 56.7)	36.2	(27.5 – 45.7)	69	0.234
2nd quintile	35.5	(23.7 – 48.7)	44.0	(34.8 – 53.5)	73	
3rd quintile	19.4	(10.4 – 31.4)	12.1	(6.8 – 19.4)	26	
4th quintile	1.6	(0.0 – 8.7)	6.0	(2.5 – 12.0)	8	
5th quintile (least deprived)	0.0	(0.0 – 5.8†)	1.7	(0.2 – 6.1)	2	
Education						
Entry Level – Level 2	8.1	(2.7 – 17.3)	6.0	(2.5 – 12.0)	12	0.760
Level 3 - 5	24.2	(14.2 – 36.4)	28.5	(20.5 – 37.6)	48	
Level 6 - 8	67.7	(54.7 – 79.1)	65.5	(56.1 – 74.1)	118	
Employment						
Employed	53.2	(40.1 – 66.0)	49.1	(39.7 – 58.6)	90	0.482
Student & Employed	12.9	(5.7 – 23.9)	9.5	(3.8 – 16.3)	11	
Student	25.8	(15.5 – 38.5)	36.2	(27.5 – 45.7)	58	
Unemployed	8.1	(2.7 – 17.8)	5.2	(1.9 – 10.9)	19	

Confidence interval, CI; Index of Multiple Deprivation, IMD
†one-sided, 97.5% CI

7.6.2 Service Ratings

There were significant differences in the Likert responses to three out of the five service rating statements as shown in Table 7-3. In response to the statement “it was convenient to access the pill from this service”, 85.5% (95% CI 74.2 – 93.1) of the online contraception group strongly agreed whilst 42.2% (95% CI 33.1 – 51.8) strongly agreed in the other services group ($p<0.001$). In response to the statement “it would be easy to ask questions or communicate with the service if I had any problems with my contraception over the next three months”, 50.0% (95% CI 37.0 – 63.0) of the online contraception group strongly agreed and 31.9% (95% CI 23.6 – 41.2) strongly agreed in the other services group ($p<0.001$). The third statement was concerning speed - “getting oral contraceptive pills from this service was too slow”, and 67.7% (95% CI 54.7 – 79.1) of the online contraception group strongly disagreed with this compared to 34.5% (95% CI 25.9 – 43.9) in the other services group ($p<0.001$). Responses to statements about privacy, information and choice were not significantly different between the two groups.

Table 7-3 Service Ratings Comparing Those Accessing Online Contraception to Those Using Other Services (n=178)

	Online contraception (SH:24) (n=62)		Other services (n=116)			
	%	95% CI	%	95% CI	N	p value (X^2)
I did not have enough privacy when using this service						
Strongly agree 1	4.8	(1.0 – 13.5)	3.5	(1.0 – 8.6)	102	0.145
2	3.2	(0.4 – 11.2)	6.9	(3.0 – 13.1)	37	
Neutral 3	17.7	(9.2 – 29.5)	8.6	(4.2 – 15.3)	20	
4	11.3	(4.7 – 21.9)	22.4	(15.2 – 31.1)	10	
Strongly disagree 5	62.9	(49.7 – 74.8)	58.6	(49.1 – 67.7)	9	
It was convenient to access the pill from this service						
Strongly agree 1	85.5	(74.2 – 93.1)	42.2	(33.1 – 51.8)	102	<0.001**
2	6.5	(1.8 – 15.7)	18.1	(11.6 – 26.3)	25	
Neutral 3	1.6	(0.0 - 8.7)	13.8	(8.09 – 21.4)	17	
4	3.2	(0.4 – 11.2)	12.9	(7.42 – 20.4)	17	
Strongly disagree 5	3.2	(0.4 – 11.2)	12.9	(7.42 – 20.4)	17	
It would be easy to ask questions or communicate with the service if I had any problems with my contraception over the next three months						
Strongly agree 1	50.0	(37.0 – 64.0)	31.9	(23.6 – 41.2)	68	0.027*
2	19.4	(10.4 – 31.4)	30.2	(22.0 – 39.4)	47	
Neutral 3	24.2	(14.2 – 36.7)	18.1	(11.6 – 26.3)	36	
4	4.8	(1.0 – 13.5)	12.1	(6.8 – 19.4)	17	
Strongly disagree 5	1.6	(0.0 – 8.7)	7.8	(3.6 – 14.2)	10	
Getting oral contraceptive pills from this service was too slow						
Strongly agree 1	1.6	(0.0 – 8.7)	17.2	(10.9 – 25.4)	21	<0.001**
2	3.2	(0.4 – 11.2	12.1	(6.8 – 19.4)	16	
Neutral 3	9.7	(3.6 – 19.9)	19.0	(12.3 – 27.3)	28	
4	17.7	(9.2 – 29.5)	17.2	(10.9 – 25.4)	31	
Strongly disagree 5	67.7	(54.7 – 79.1)	34.5	(25.9 – 43.9)	82	
I received all the information about contraception that I needed from this service						
Strongly agree 1	66.1	(53.0 – 77.7)	52.6	(43.1 – 61.9)	102	0.509
2	17.7	(9.2 – 29.5)	22.4	(15.2 – 31.1)	37	
Neutral 3	8.1	(2.7 – 17.8)	12.9	(7.4 – 20.4)	20	
4	4.8	(1.0 – 13.5)	6.0	(2.5 – 12.0)	10	
Strongly disagree 5	3.2	(0.4 – 11.2)	6.0	(2.5 – 12.0)	9	
This service limited my contraceptive choices						
Strongly agree 1	8.1	(2.7 – 17.8)	3.5	(1.0 – 8.6)	9	0.098
2	19.4	(10.4 – 31.4)	7.8	(3.6 – 14.2)	21	
Neutral 3	24.2	(14.2 – 36.7)	25.9	(18.2 – 34.8)	45	
4	17.7	(9.2 – 29.5)	23.3	(15.9 – 32.0)	38	
Strongly disagree 5	30.7	(19.6 – 43.7)	39.7	(30.7 – 49.2)	65	

Confidence interval, CI
* p value significant <0.05
** p value significant <0.001

The numerical values of the each of the service rating scores were totalled and the means of these totals were compared between the two service use groups. Table 7-4 show that there was a significant difference observed between the means for the online group (mean=25.32; SD=3.75) versus the other services group (mean=22.93; SD=4.29) (p<0.001) indicating more positive service ratings for the online contraception service.

Table 7-4 Mean Service Rating Scores Comparing Those Accessing Online Contraception to Those Using Other Services (n=178)

Online contraception (SH:24) (n=62)		Other services (n=116)		
Mean	SD	Mean	SD	p value
25.32	3.75	22.93	4.29	<0.001**

Standard deviation, SD
* p value significant <0.001

7.6.3 Service Rating: Free Text Responses

A total of 93 participants (online contraception n=67; other services n=26) provided data in the form of a free text response regarding contraception services in Lambeth and Southwark. Several comments were general and mostly positive about both the online and other services.

> "SH:24 is a great service"
>
> "Really good at Camberwell"
>
> "The contraception services in Lambeth and Southwark are great"

1. Privacy

There were no references to privacy, anonymity or related concepts found in the analysis of free text responses.

2. Convenience

Convenience was mentioned frequently, with largely positive statements found in those who were in the online contraception group.

> "Convenient to order pills online rather than make appointment"

There were a small number of positive statements about other services, in particular those that mentioned the ease with which additional services could be accessed during the same consultation.

> "The walk in centre was fantastic – they saw me the same day…as well as giving me the morning after pill gave me full STI check and spent time matching me with the best pill"

However, some of those in the other services group were highly critical of service quality in this area, often mentioning difficulties in accessing providers during their opening hours.

> "I have had to take unpaid time off work in order to get my pill."

3. Communication

Very few of the comments from those in the online contraception group mentioned communication-related issues, but those that did were positive about the nature and the method of communication employed.

> "helpful they contact you by text"
>
> "The service contacted me to ensure that I had received the pills and that I was ok."

There was a more mixed set of responses around communication within other services. There was even a combination of positive and negative experiences of communication within the same responses, some highlighting inconsistencies in the standard of communication from different staff within one service, and others mentioning that they preferred interactions in one face to face service over another.

> "The first lady I saw took time to explain all the different types of contraception and gave me time to make a decision. However, with the man I saw the next time I felt quite rushed to make a decision…"

4. Speed

Speed was the most frequently mentioned area of service quality in the free text responses. All those who provided responses from the online group spoke highly of the speed of the service.

> "It is very useful services and sends very quickly"

Overall, the length of waiting times was repeatedly mentioned as a disadvantage of community clinic services with some stating that this was a barrier to attendance.

> "The waiting time in Camberwell centre is too long. Sometimes puts me off and in the past I have left when I really need to see someone."

5. Information delivery

The quality of information was not mentioned by those from the online contraception group, although there were two comments which indicated a positive response to receiving text messages (see communication section). Those in the other services group appeared to appreciate the time and care taken by staff to explain information about contraception to them.

> "They have informative staff"

> "Explained a lot to me and made me feel like I could go back anytime for any reason"

6. Choices

There was one comment that indicated disappointment that the online service was not able to offer "different brands". Apart from this, statements about choice took a broad overview of the landscape of services in the area, some of which were positive about the options available (particularly those that appeared to be aware of the online service), and others being more critical, citing areas where options were limited or required further resources.

> "There are multiple service providers which fit the needs of everyone"

> "It's great that there are more and more options available."

> "I feel as if there needs to be more services in Southwark"

> "Just wish there was a pile more option for weekend visits"

7.6.4 Knowledge Scores

Tables 7-5 and 7-6 present proportions, ORs, and risk differences for participants answering the knowledge questions correctly, according to type of service accessed. The majority of participants providing data on knowledge relating how to safely and effectively use OCPs, answered questions regarding COC-use (61.1%). This includes 8 participants who stated they were unsure of their pill type who were directed to questions relevant for COC-users (online contraception n=2; other services n=6). There were no statistically significant differences observed (in either the OR risk difference) for any of the COC knowledge questions when comparing participants responding with correct answers in the online contraception group to the other services group (Table 7-5). Both groups had large proportions with correct answers for some questions including those concerning the recognition of side-effects requiring medical attention (85.3% versus 86.3%) and knowledge of the need for EC in a scenario about missed pills (91.2% versus 91.8%). Both groups had relatively smaller proportions correctly answering a question about whether COC use was associated with weight gain (32.4% versus 42.5%).

Table 7-5 Proportion of Correct† Responses to OCP Knowledge Questions for Participants Self-Reporting COC use Comparing Those Accessing Online Contraception to Those Using Other Services (n=107)

	Online contraception (SH:24) (n=34)		Other services (n=73)					
	%	95% CI	%	95% CI	OR (95% CI)	p value	Risk difference (95% CI)	p value
Questions for self-reporting COC use								
Recognition of side-effects requiring medical attention	85.3	(68.9 – 95.1)	86.3	(76.3 – 93.2)	0.92 (0.29 – 2.94)	0.889	-1.01 (-15.29 – 13.27)	0.889
Recognition of infertility myth	73.5	(55.6 – 87.1)	72.6	(60.9 – 82.4)	1.05 (0.42 – 2.63)	0.920	0.93 (-17.09 – 18.94)	0.920
Recognition of weight myth	32.4	(17.4 – 50.5)	42.5	(31.0 – 54.6)	0.65 (0.28 – 1.52)	0.320	-10.11 (-29.50 – 9.27)	0.319
Knowledge of time required for additional contraception if missed pill	79.4	(62.1 – 91.3)	91.4	(81.2 – 96.1)	0.41 (0.13 – 1.28)	0.124	-11.00 (-26.18 – 4.18)	0.116
Knowledge of pill break avoidance if missed pill	61.8	(43.6 – 77.8)	63.0	(50.9 – 74.0)	0.95 (0.41 – 2.19)	0.871	-1.25 (-20.98 – 18.49)	0.901
Knowledge of when to get EC if missed pill	91.2	(76.3 – 98.1)	91.8	(83.0 – 96.9)	0.93 (0.22 – 3.94)	0.745	-6.04 (-12.03 – 10.82)	0.917
Knowledge of what to do if vomiting occurs after taking a pill	70.6	(52.5 – 84.9)	79.5	(68.4 – 88.0)	0.62 (0.24 – 1.57)	0.315	-8.86 (-26.77 – 9.04)	0.313

† Correct responses include both ideal and acceptable responses to the multiple choice questions

Oral contraceptive pills, OCPs; combined oral contraception, COC; odds ratio, OR; confidence interval, CI emergency contraception, EC

Table 7-6 Proportion of Correct† Responses to OCP Knowledge Questions for Participants Self-Reporting POP use Comparing Those Accessing Online Contraception to Those Using Other Services (n=68)

	Online contraception (SH:24) (n=27)		Other services (n=41)					
	%	95% CI	%	95% CI	OR (95% CI)	p value	Risk difference (95% CI)	p value
Questions for self-reporting POP use								
Recognition of the impact on bleeding patterns	44.4	(25.5 – 64.7)	36.6	(22.1 – 53.1)	1.39 (0.52 – 3.73)	0.518	7.86 (-15.99)	0.517
Recognition of infertility myth	96.3	(81.0 – 99.9)	70.7	(54.5 – 83.9)	10.76 (1.31 – 88.52)	0.027*	25.56 (9.92 – 41.21)	0.009*
Recognition of weight myth	18.5	(6.3 – 38.1)	24.4	(12.4 – 40.3)	0.70 (0.21 – 2.35)	0.569	-5.87 (-25.56 – 13.81)	0.568
Knowledge of time required for additional contraception if missed pill	55.6	(35.3 – 74.5)	61.0	(44.5 – 75.8)	0.80 (0.30 – 2.14)	0.657	-5.42 (-29.38 – 18.54)	0.657
Knowledge of when to get EC if missed pill	85.2	(66.3 – 95.8)	90.2	(76.9 – 97.3)	0.62 (0.14 – 2.73)	0.529	-5.06 (-21.25 – 11.13)	0.526
Knowledge of what to do if vomiting occurs after taking a pill	85.2	(66.3 – 95.8)	78.1	(62.4 – 89.4)	1.62 (0.44 – 5.90)	0.467	7.14 (-11.30 – 25.58)	0.464

† Correct responses include both ideal and acceptable responses to the multiple choice questions

Oral contraceptive pills, OCPs; progesterone only pill, POP; odds ratio, OR; confidence interval, CI emergency contraception, EC

A smaller proportion of the 175 participants self-reported POP-use and thus answered POP-related questions (38.9%) shown in Table 7-6. There were significantly more people in the online services group who correctly responded to the question on the recognition of the myth that infertility was associated with POP-use, with a statistically significant risk difference of 25.56 (95% CI 9.92 – 41.21, p value=0.009) and an OR of 10.76 (95% CI 1.31 – 88.52; p=0.027). There were no further statistically significant findings in risk difference between proportions with correct answers or the ORs for any other questions. Both groups had small proportions with correct answers for the question about recognising the impact of POP on bleeding patterns (44.4% versus 36.6%) and recognition of the weight gain myth (18.5% versus 24.4%). Both groups had larger proportions correctly answering the question about the need for EC in the event of a missed pill (85.2% versus 90.2%) and what to do in the event of vomiting whilst on the pill (85.2% versus 78.1%).

Correct responses to knowledge questions were assigned numerical values and totalled for each of the exposure groups according to self-reported OCP type and the means for these totals are presented in Table 7-7. There was no significant difference observed between the means for the online group (mean=9.29; SD=2.44) versus the other services group (mean=9.88; SD=2.30) (P=0.234) for self-reported COC users. Although there was a slightly higher mean for POP users in the online group (mean=7.37; SD=2.54) compared to the other services group (mean=6.78; SD=1.94), the difference was also non-significant (p=0.142).

Table 7-7 Mean OCP Knowledge Scores Comparing Those Accessing Online Contraception to Those Using Other Services (n=175)

	Online contraception (SH:24) (n=61)		Other services (n=114)			
	Mean	SD	Mean	SD	N	p value
Self-reported COC user[†]	9.29	2.44	9.88	2.30	107	0.234
Self-reported POP user	7.37	2.54	6.78	1.94	68	0.142

[†]Includes 8 participants who stated they were unsure of their pill type who were directed to questions relevant for COC-users (online contraception n=2; other services n=6)
Self-reported COC users could score a maximum of 14 points and POP users could score a maximum of 12 points.
Combined oral contraception, COC; progesterone only pill, POP; standard deviation, SD

7.7 Discussion

7.7.1 Key Findings

Those participants who used the online contraception service for their first supply of OCPs rated their service more highly than those using other services in the areas of convenience; communication and speed. The total service rating score was slightly higher for the online group versus the other services group and there was a statistically significant difference between the means.

Analysis of the free text responses on contraceptive service quality provided some further detail about the areas which were perceived positively and negatively, including some more nuanced responses and perceptions about the landscape of services overall. In some ways, these free texts responses reflected the findings from the analysis of the scale responses to quality, with participants speaking highly of the convenience and speed of online access and being decidedly critical of long waiting times and inconvenient opening hours in community clinics. Communication was a complex marker of quality for those in the other services group, with participants citing both negative and positive interactions from different staff members and services. In terms of choice, participants perceived online services as an expansion of choice, adding to existing contraceptive options already available.

There were no significant differences for any of the COC knowledge questions when comparing participants responding with correct answers in the online contraception group to the other services group. Similarly, there were no differences in the analysis of correct responses to the POP knowledge questions, except for the recognition of the myth that infertility was associated with POP-use, for which the odds of a correct response was higher in the online group.

7.7.2 Methodological Considerations

Strengths

The service rating outcomes of the CiP-CO study provide insight into the attributes of the online contraception service which are valued by those accessing it for their first supply of OCPs. The design of the entire study, and particularly the service rating component of the questionnaire, has a strong theoretical basis, with in-depth formative qualitative research (Chapter 4) and understanding of the literature used to determine the relevant aspects of quality to include. Secondly, these findings were bolstered, and greater richness added, through giving participants the opportunity to respond to an open-ended question about their overall perception of contraception provision in their area.

SH:24's online contraceptive service represents a fundamental shift in the way contraceptive counselling and the clinical consultation process are delivered to OCP users. Therefore, testing the differences in OCP knowledge about safe and effective pill use between the online group and other services group is imperative for understanding the impact of such a shift in the delivery of contraceptive consultations. These questions were developed with careful consideration of the guidelines and literature and were strengthened through repeated piloting with clinical staff, who were current contraceptive prescribers, and with potential participants.[2]

[2] Participants were also asked to provide a free text response to the question, "Please provide any additional comments about the CiP-CO study", which received several positive statements about the knowledge component of the questionnaire and how it encouraged more active consideration of the safe and effective use of OCPs, see Appendix S for further details.

Limitations

The limitations regarding sample size, recruitment and attrition issues of the CiP-CO study that were discussed in section 6.7.2 have also diminished the strength of the outcomes in this chapter to facilitate conclusive understanding of the online service. This is most apparent when considering the POP knowledge outcomes for which only 68 participants had available data (online service n=27; other services n=43) so were highly likely to have been underpowered for detection of statistically significant differences. In the light of this small sample size, it may well be that the significantly greater recognition of the myth that infertility was associated with POP-use among the online-users was a spurious finding. Furthermore, the large confidence intervals around the OR (OR 10.76; 95% CI 1.31 – 88.52; p=0.027) indicate the imprecision of the result.

An expert review of this thesis following analysis and write-up established that scenarios 1 and 2 in the knowledge questions (Table 7-1) provided insufficient information for participants to accurately arrive at the correct responses (Chen ZE [Researcher, Faculty of Sexual & Reproductive Healthcare Clinical Effectiveness Unit (FSRH CEU)] 2019, oral communication, 26th April). Participants were not provided with information regarding the fictional characters' pill use in the 7 days prior to their missed pills, thus these questions have subsequently been considered invalid. Reanalysis of the data with these questions excluded from the total knowledge scores maintained the finding that there was not a statistically significant difference between the mean knowledge scores for the online group compared to the other services group for those self-reporting COC use (online service mean=4.53, SD=1.69; other services mean=4.82, SD=1.58; p=0.3861) or POP use (online service mean=4.04, SD=1.56; other services mean=3.41, SD=1.56; p=0.1125). Following the removal of these questions, self-reported COC users and POP users could score a maximum of 8 points.

Whilst it was deemed useful to provide summary measures of both the service rating scores and the knowledge scores for an overall indication of how the outcomes differed between exposures, these results should be interpreted with caution. The questions within each were designed as single-item measures to directly assess each aspect of knowledge and each domain of service quality. They were intended to have strong content and face validity and to not over-extend the questionnaire and lead to fatigue of the participants. They were also not overtly designed to be analysed as scales with their own internal consistency. For example, participants may be highly knowledgeable about missed pill guidelines, but unable to discern myths related to side-effects, perhaps due to their own experiences or their interpretation of anecdotal evidence. Similarly, for service rating outcomes, the online service appears to be perceived as highly convenient, but not particularly conducive to facilitating choice, however, may still be viewed favourably in terms of overall quality despite these contradictions, as choice might not be a priority for users of the online service.

The free text responses give an indication of some of the nuances in these interpretations of service quality. However, this opportunity for participants to share their feedback to an open-

ended question about services came only once and very near to the end of the final questionnaire, by which point they may have been fatigued or dropped out. In addition, the qualitative analysis was deductive using the framework for aspects of quality determined a priori. Hence, privacy, which was considered an important aspect of the service through the development of the theory of change with stakeholders, was not mentioned by participants in the free text responses. This is potentially because stakeholders from SRH clinical environments conflated the inputs that would be of value within STI services with those salient to contraceptive services alone.

The final limitation to consider is that as an observational study, the knowledge outcomes have the potential to be a result of variables unrelated to the nature of the service accessed. Whilst there were no significant differences in the sociodemographic variables between groups, it is still likely that knowledge outcomes have been affected by confounding. The sample size was insufficient to conduct adjusted analyses to test the strength of the association between knowledge outcomes and type of service used for OCPs.

7.7.3 Findings in Relation to Other Studies

These findings broadly correspond to those in the wider literature. Convenience is typically valued by those choosing online services over accessing face-to-face. A US study looking at women who accessed EC over the internet cited that structural barriers such as inconvenient opening hours, as the most important reasons for accessing this service over face-to-face alternatives (342). The online contraception service involves text messaging for communication, including routine messages confirming OCP deliveries, reminder texts about accessing another OCP supply, and the option for service-users to proactively text their providers for advice or information. Remote communication via text messaging has also proven to be effective in improving contraceptive knowledge in low-income settings (43, 300) and in the US (44, 45), although outcomes pertaining to perceptions of or preferences for this method of communication were not reported.

There are also studies that support the capacity of online or digital interventions to convey complex SRH information. A US study indicated that a computer-based intervention can positively influence contraceptive method choice with family planning patients who used the module significantly more likely to choose an effective contraceptive method (OR=1.56; 95% CI 1.23–1.98) compared to the control arm (38). A systematic review of interactive computer-based interventions, found that compared to minimal interventions, there were significant effects on sexual health knowledge (standardised mean difference [SMD] 0.72; 95% CI 0.27–1.18) although outcomes specific to contraceptive knowledge were not reported (164).

7.7.4 Findings in Relation to Conceptual Model and Theoretical Framework

Participants who used the online contraception service (SH:24) for their first supply of OCPs rated their service more highly than those using other services in terms of convenience, speed of access to OCPs and ease of communication with provider, which may be indicative of why short term OCP continuation was more likely in the online compared to the other services group for the primary outcome results in Chapter 6. These findings also support the predictions in Chapter 4 that the online service, particularly the input of home delivery of contraception would be perceived as convenient and that there would be preferences for remote interaction with contraceptive provider in the community. There were no differences in how the online service and other services were rated in terms of privacy and no mentions of privacy or anonymity in free text responses, contradicting the prediction in the ToC model that online access could enhance anonymity. In response to the statement, "I did not have enough privacy when using this service", there was 62.9% strong disagreement in the online group; very slightly higher than the other services group in which 58.6% strongly disagreed. Privacy was not mentioned within the free text responses which could indicate a lack of salience of this indicator of quality among the participants.

A key process in the ToC model was that online consultation and information about contraception was assumed to elicit greater autonomy in contraceptive decision-making through enhanced trust in service-users' capabilities to take on information remotely (Figure 4-2). This was the positive process of change, but the qualitative interviews with stakeholders also revealed fears and concerns about the extent to which complex information could be understood without the face-to-face interaction with a provider. There were no significant differences in the proportions responding correctly to knowledge questions, and one question for which the odds of a correct response was greater in the online group, which is reassuring about the extent to which OCP users have the knowledge to safely and effectively use their contraception when accessing OCPs online. However, these service-users could be considered unusual in that they have accessed a new, and not widely publicised service and they have chosen to participate in research, hence results may not be generalisable to the wider population of OCP users or extend to the more vulnerable and complex cases highlighted as having the potential to misunderstand online advice by stakeholders in Chapter 4.

The aspect of the Bourdieusian theoretical framework to which the findings of this study are most apposite for discussion is the concept of capital. This is described in Chapter 3 as the cultural or social resources that actors exercise consciously or subconsciously within social interactions that function as a "social relation of power" (218, 236). The outcomes on basic OCP knowledge are a form of capital, which enable safe and effective contraceptive practice. There was very little difference in these outcomes between the online group and other services group, suggesting that there is parity in the effectiveness of conveying capital in patient-provider interactions whether they are conducted digitally and remotely or face-to-face.

The online service scored more highly than other services in the domains of convenience, communication and speed of access to OCPs. In Chapter 3 it was discussed that physical

services also require the deployment of capital, not just during the consultation but also during the process of acquiring an appointment and getting to a service. The online service does not require this capital which may be why it is considered both convenient and speedy. With regard to communication, it could be said that through providing supportive provider contact beyond the consultation, the text messaging interventions help to account for the complexities of contraceptive decision-making that extend into everyday life, particularly for methods like OCPs which require daily adherence, thus contributing to effective contraceptive practice.

The qualitative findings in section 7.6.3 are valuable in transcending the objective/subjective dichotomy which is central to Bourdieu's ontological approach. Considered through a Bourdieusian lens, they are indicative of some aspects of habitus and are revealing of the expectations and perceptions of patient-provider interactions. It was emphasised in the free text responses that those of a habitus involving busy lifestyles and full-time work could preclude use of face-to-face providers, leading to limited choice and possibly ineffective contraceptive practice.

> "I have had to take unpaid time off work in order to get my pill."

Some of the literature discussed in Chapter 3 emphasised the uniqueness of contraceptive practice to warrant greater patient agency in decision-making, however several of the free text responses revealed an appreciation and desire for more provider support and personalised guidance.

> "The first lady I saw took time to explain all the different types of contraception and gave me time to make a decision. However, with the man I saw the next time I felt quite rushed to make a decision…"

> "The service contacted me to ensure that I had received the pills and that I was ok."

The Bourdieusian theoretical framework is useful in emphasising that it is important to consider online contraception not as an alternative to face-to-face services but as an expansion in the existing landscape of provision. Those accessing different types of providers are not easily delineated and categorised according to distinct social groups and lifestyles and it is likely that people will navigate within and between different services according to their changing needs and circumstances.

> "There are multiple service providers which fit the needs of everyone"

7.7.5 Implications

The service rating outcomes of the CiP-CO study provide insight into the attributes of the online contraception service which are valued by those accessing it for their first supply of OCPs. There are no other free-to-access, online contraceptive services of this type that have been evaluated in the literature or that have been available to this population, so understanding these markers of quality are highly important for the development of the nascent service and for decision-making on if, and in what form, an intervention of this type should be extended to a larger population.

In addition to indicating which areas of quality scored highly, the study also suggests where the online service could improve, or indeed where it may have limited scope as a provider. The online service did not score differently to other services in areas of privacy; information and choice. These results are indicative that across these domains, the online contraceptive service is not perceived differently to other services. However, when considering these areas in combination with the analysis of the free text responses it could be suggested that: 1) whilst remote interaction after the initial consultation is valued, it can be preferable to receive complex, contraceptive information within a face-to-face environment, although consistency in the quality of these interactions can be difficult to achieve and; 2) contraceptive choice is viewed by OCP-users as relating to the entire landscape of providers, with online OCPs as a valuable new option within a range of different services and methods.

The importance of contraceptive counselling and the clinical consultation process in enabling women to safely and effectively use their OCPs is consistently emphasised in national (83, 87) and international guidelines (343). With the exception of the question relating to the association between POPs and infertility, there were no differences in either COC or POP knowledge between the two service groups, perhaps indicating that there is little difference in the knowledge that can be absorbed or accessed after an online compared to a face-to-face consultation. This is reassuring about the capacity for service-users to understand and interpret complex, contraceptive information online to an equivalent standard to that which is achieved within community clinic or GP services. However, it is concerning that in some areas, such as being able to recognise that use of OCPs is not linked to weight gain, both exposure groups scored poorly, suggesting that improvements in the counselling and information-giving aspects of consultations within all services could benefit from improved consistency and quality.

7.7.6 Directions for Future Research

The free text responses, as well as findings around service ratings and knowledge indicate where both types of service delivery could improve and how they could be developed to complement one another. This more holistic appreciation can be lost through purely quantitative analytical approaches which posit one exposure against the other. Whilst providing a valuable insight into the complex factors involved in contraceptive practice, the study is limited in its appreciation of the subjective perceptions and experiences of the participants. Firstly, more complex, rigorously validated questionnaires could be developed for further understanding of each aspect of service quality, with enough measures to cover the various interpretations of each of the domains. Secondly, in-depth interviews with OCP users, would facilitate a more inductive analysis of perceptions of the different services, which may reveal topics beyond the domains of quality that were determined and analysed according to the findings of the ToC study (Chapter 4). This is likely to be useful for quality improvement across all forms of contraceptive services, both online and face-to-face.

As stated in Chapter 6, an RCT is recommended to randomly allocate OCP users to either the online or other services exposures, thus minimising the potential for confounding. This would provide more conclusive evidence that an online consultation does not diminish the level of basic OCP knowledge retained relative to face-to-face services. This and other suggestions for future research will be further discussed, along with the overall thesis findings, methodological considerations and implications, in the following chapter.

7.8 Summary of Chapter 7

- Those participants who used the online contraception service (SH:24) for their first supply of OCPs rated their service more highly than those using other services in the areas of convenience; communication and speed of access to OCPs.
- There were no differences in rating scores relating to privacy; information and choice, which, in conjunction with the free text responses on contraceptive service quality, suggests that 1) contraceptive information can be effectively, if inconsistently provided within a face-to-face environment and; 2) online contraception introduces more choice in addition to, rather than independently of, the existing landscape of providers.
- There were no significant differences in the proportions responding correctly to knowledge questions, except for the recognition of the myth that infertility was associated with POP-use, for which the odds of a correct response was higher in the online group.
- There are no other online contraceptive services of this type that have been evaluated in the literature or that have been available to this population, so understanding these markers of quality are important for the development of the nascent service and for decision-making on if, and in what form, a service of this type should be extended to a larger population.
- SH:24's online contraceptive service represents a fundamental shift in the way contraceptive counselling and the clinical consultation process are delivered to OCP users. The findings relating to knowledge are reassuring about the capacity for service-users to understand and interpret complex, contraceptive information to an equivalent standard to that which is achieved within community clinics or general practice.

8 Discussion

8.1 Chapter Overview

The aim of this thesis, outlined in section 1.3, was to evaluate the impact of online contraception in Lambeth and Southwark. This chapter presents a critical appraisal and discussion of the findings of the research conducted to meet this aim. It also presents the implications for the future of the online service within the current context of contraceptive provision and makes recommendations for the direction of research on online contraception and related fields.

8.2 Summary of Findings

The overarching theoretical framework used Bourdieu's Theory of Practice to consider contraceptive activities as practice; involving the day-to-day, routinised decision making which is generated by habitus, with access to supplies and information requiring interaction with health professionals within the field of contraceptive healthcare. This interaction requires contraceptive-users to deploy and possibly acquire forms of capital, such as the knowledge and skills to choose and access a contraceptive method that is appropriate and effective. The Bourdieusian perspective reconfigured the intervention of online contraception as a structural shift in provision and new field of access that could fundamentally alter the contraceptive patient-provider interaction, giving contraceptive service-users in Lambeth and Southwark greater agency in terms of access to information, but also greater choice in terms of the mode of access to OCPs and the option to communicate with their contraceptive provider remotely, including through use of text messaging.

However, such positive effects were considered as contingent upon the expenditure of capital and the habitus required for effective access within the wider landscape of provision. Whilst online access requires familiarity with Internet services and cultural capital in the form of e-health literacy, this could be seen as relatively less taxing than the capital required to overcome challenges of access to community clinics and GPs, such as knowledge of services, skills in communication with staff and the time and effort required for travel to and attendance at face-to-face services. The capacity for habitus to engender homogeneity in social groups and the nature of capital to be unequally distributed in society raised the question of whether the introduction of online contraception into this wider landscape of providers could serve to alleviate or exacerbate health inequalities in effective contraceptive practices. Ideally, the introduction of online services into the wider landscape of provision would facilitate service-users navigating within and between their different provider and method options depending on their circumstances and preferences in a way which would be choice-enhancing. However, even when viewing the online service as an additional option of access rather than a standalone service, there could be concerns about the extent to which capital, in terms of the knowledge and skills to ascertain the most appropriate and effective provider for a given requirement, may be unevenly distributed across society.

This broader, sociological framework was integrated with a more focused and context-specific ToC conceptual model. This depicted the positive processes of change that stakeholders predicted could be initiated through the introduction of the online service (Figure 4-2). It was predicted that it could offer convenience, anonymity, autonomous access, responsive support and expanded choice of service but that only those with particular perceptions and characteristics, such as being familiar with and trusting of online services, would be likely to benefit from key intervention inputs. The narrative accompanying the ToC model explored some of the potential risks of the online service, stressing the importance of meeting the varied needs of a diverse population, in particular those who may be young and in need of more supportive, complex care, and the value of maintaining existing contraceptive choices through integrating the intervention within the wider landscape of provision.

The online service's routinely collected data generated through their OCP ordering process was used to conduct an exploratory quantitative study to determine service-user characteristics and patterns of use during its first 15 months of availability to residents of Lambeth and Southwark. During this time, it was accessed 1186 times by 726 unique individuals. Almost three quarters of the sample were aged between 20 and 29 years and most were of white ethnic group. Nearly 80% were residents of areas in the 1st and 2nd most deprived IMD quintiles. The majority of service-users made at least one complete order and a third made at least two complete orders. Among these service-users with repeat orders, nearly two thirds had a time interval between their 1st and 2nd order that was sufficient to provide contraceptive coverage. Compared with individuals reported as being of white ethnic group, those of black ethnic group were significantly less likely to have repeat orders; an association which remained significant in the multivariable analysis which adjusted for all available sociodemographic variables. This was also the case for both the Asian and mixed ethnic groups.

The CiP-CO cohort study compared online users with those using other services for their first supply of OCPs using a combination of questionnaire data and objective data from the contraceptive services used by participants. Those participants who used the online contraception service for their first supply of OCPs were significantly more likely to experience short-term continuation of this method compared to participants using other services (mostly community clinics and GPs), and this strong positive association remained after adjusting for ethnicity, age, IMD, education, employment status, smoking status and reported likelihood of taking the prescribed OCPs. There was no difference in the timing of access to the next prescription of OCPs between those who continued in the online group compared to those who continued in the other services group.

Compared to participants in the other services group, those participants who used online contraception rated their service more highly in terms of convenience, speed of access to OCPs and ease of communication with provider. There was a statistically significant difference between the mean overall service rating score, which was higher for the online group compared

to the other services group. Analysis of free text responses on contraceptive service quality emphasised the appreciation among online users of supportive texts and the convenience and speed of access. In comparison, those accessing community clinics expressed irritation with long waiting times and inconvenient opening hours but some positive responses about informative and helpful interactions with staff. There were no significant differences in the proportion of correct responses to COC knowledge questions when comparing the online contraception group to the other services group. Similarly, there were no differences in the analysis of correct responses to the POP knowledge questions, except for the recognition of the myth that infertility was associated with POP-use, for which there were significantly more correct responses in the online group.

8.3 Methodological Considerations

8.3.1 Strengths

This application of Bourdieu's Theory of Practice represents a unique contribution to the literature on contraception which is largely dominated by theoretical underpinnings using social cognitive models. It has been a useful theoretical framework through which to consider contraceptive practice as distinct from other areas of health, with its focus on patient agency in terms of method choice and in the nature of pregnancy as an ambiguous outcome that can elicit a range of responses. This sociological lens has allowed a more abstract assessment of the literature on remote and digital interventions; and building from this, facilitated consideration of how the novel online contraceptive service could alter existing models of provision. Furthermore, it has provided a lens through which to contextualise the empirical findings within a wider, societal perspective and an ontological position through which to interpret the limitations of the studies and their results.

This qualitative study in Chapter 4 surfaced and interrogated the implicit assumptions underpinning the processes of change predicted to ensue following the introduction of online contraception in Lambeth and Southwark. This has been essential in the absence of a precedent in the literature for an intervention of this complexity, scale and within a context of free contraceptive provision and disproportionately poor reproductive health outcomes. The resulting ToC conceptual model (Figure 4-2) encapsulated a range of stakeholder viewpoints facilitating hypothesis generation for the empirical studies and contributing to elements of the study design and interpretation of findings, such as the design of the service rating component of the CiP-CO questionnaire and the deductive analysis of the free-text responses in section 7.6.3. The ToC approach is advocated for its flexibility and pragmatism to real-life contexts. It proved a responsive and useful tool to generate new study designs after the original EC protocols (Appendices A and B) could no longer be implemented.

The ToC findings also provided some specific conditions for the application of the sociological concepts in the theoretical framework, including areas of potential power struggle in an altered

field of contraception. It also framed consideration of the concept of “younger generations” which stakeholders perceived to be a key determinant of use, positing this as a driving factor of Internet habitus in which e-health capital and preferences for online services could accumulate.

Chapter 5 presented the first study to describe users of a free to access, NHS commissioned, online contraception service. Understanding the characteristics of those who have been drawn to access and repeatedly use an online service was important exploratory work for establishing whether it could meet the contraceptive needs of the target population. Through describing patterns of service-use, it provided some medically relevant outcomes regarding the service-users’ experiences of the intervention and the quality of care they received, namely the proportion of service-users who returned to order repeat supplies and who did so without apparent gaps in coverage; gaps which could potentially put them at risk of unplanned pregnancy. Finally, in determining BAME groups as those less likely to repeat their OCP online orders compared to those of white ethnic group, this study has indicated an important area for further work and consideration, particularly as these are ethnically diverse boroughs in which poorer reproductive health outcomes have been reported in black ethnic groups.

The CiP-CO study was a multi-site cohort study and the first to compare outcomes relating to contraceptive continuation between participants accessing a free, NHS commissioned, online contraception service and those accessing GPs and SRH services for their 3 months’ supply of OCPs. By capturing data on OCP service-use from such a range of providers in Lambeth and Southwark, the outcomes of this study were informative of service-users’ contraceptive access and decision-making across the landscape of providers in the area. Despite the problem of under-recruitment and the study being underpowered for its primary outcome, the difference between OCP continuation in both groups was of a sufficient magnitude for a statistically significant result to be detected. This provided the first indication that the public health impact of online contraception could be to improve short-term OCP continuation. Data sources were both self-reported questionnaires and objective, routinely-collected data from services. Self-reported questionnaires were valuable in capturing background data and the OCP knowledge and service-rating outcomes presented in Chapter 7. Objective data was essential to determine eligibility, and then to confirm the primary outcomes of continuation and time from first OCP expiry and access to second OCP supply, helping to minimise the bias which can stem from use of self-reported data sources alone.

The service rating outcomes of the CiP-CO study provided insight into the attributes of the online contraception service which were valued by those accessing it for their first supply of OCPs. The design of the entire study, and particularly the service rating component of the questionnaire, had a strong theoretical basis, with in-depth formative qualitative research (Chapter 4) and understanding of the literature used to determine the relevant aspects of quality to include. Secondly, these findings were bolstered, and greater richness added, through giving participants the opportunity to respond to an open-ended question about their overall perception of contraception provision in their area. Knowledge questions were developed with careful

consideration of the guidelines and literature and were strengthened through repeated piloting with clinical staff, who were current contraceptive prescribers, in addition to potential participants.

8.3.2 Limitations

The drawback of using an abstract, social theoretical approach is in making explicit links to studies occupying more positivist paradigms which, rather than transcending the subjectivist/objectivist divide, are often explicitly judged on their capacity to produce objective results. Whilst Bourdieu's reflexive sociology is considered to be an ideal epistemological approach to mixed methods research (278), concepts such as habitus are challenging to incorporate into quantitative study design as the factors shaping it are more complex and fluid than that which can be measured through formal social categories (225). The self-reported questionnaire developed for the CiP-CO study was designed to capture the wide-ranging factors that have been identified as being associated with effective use of contraception and related outcomes. However, this was unlikely to have sufficiently captured habitus or complex, related concepts like the interaction between age, ethnicity and social class as drivers of societal divisions and inequalities as outlined in Chapter 3.

The data sources, sampling procedures and interview guides used for the ToC study were carefully developed and employed for a dataset that captured a range of relevant stakeholder viewpoints that facilitated consideration of both the positive and negative potential consequences of the intervention. However, the approach may have limited the evaluation and prevented exploration of issues outside of those considered pertinent by the selected sample. The sample was heavily skewed toward SRH and public health professionals and the limited potential service-users included may not have captured a diverse range of viewpoints from the target population. In addition, the qualitative data was collected at an early stage of intervention development, thus required consideration of the intervention in the hypothetical sense. Many of the suggested elements of the intervention did not come to fruition during the study period. A more accurate understanding of the intervention as delivered may have resulted in a more focused and specific discussion which could have altered elements of the conceptual model.

The descriptive study in Chapter 5 was limited in its reliance upon routine data from the online service alone. As such, it did not facilitate comparisons of outcomes to OCP access in alternative providers, nor did it permit statistical comparisons between the sociodemographic characteristics of the online service-users and those of the target population. It is unknown whether patterns of service-use recorded in this dataset were representative of the participants' wider contraceptive use or actual risks of unplanned pregnancy. In addition, whilst the significant association of ethnic group with repeat ordering warrants high prioritisation for further investigation, it was unclear whether this finding was a result of factors internal or extraneous to the service.

The fundamental limitation of the CiP-CO study was that, due to low recruitment and substantial losses to follow-up, the sample size available for analysis was below the target set by the sample size calculation. Whilst the finding that OCP continuation was greater in the online group compared to the other services group was statistically significant, the result lacked precision, with large confidence intervals around the risk difference (20.44%, 95% CI 2.10 – 38.48). This low level of precision impacts how the results can be interpreted as clinically important when considering if online services can improve short-term continuation. Furthermore, there were indications of differences in outcomes between the online group and other services group, such as the smaller proportion of those in the online group reporting use of EC in the past year (39.7% versus 55.0%; p=0.097) that were likely to have been underpowered for the detection of statistical significance. Caution is needed when interpreting findings where sub-category numbers were very small, for example, ethnic group.

Recruitment procedures may have influenced the extent to which the results of the CiP-CO study reflected the characteristics of OCP users and the likelihood of short-term continuation in the general population. Participants in the other services group were mostly recruited from community clinics and some from general practice. Recruitment from more general practices and Brook services was attempted, through emails, phone calls, visits to services, meetings with staff and a posting in the Lambeth CCG GP bulletin (317), but was largely unsuccessful. Thus, the services included in the study did not reflect the range of services available in Lambeth and Southwark. Participants of the study may also have been different to the general population in having a heightened interest in contraceptive service research. Participants were given £5 cash upon completion of the first questionnaire and £10 upon completion of the second which may have introduced a bias in uptake of the study and the completion of questionnaires towards those with a particular interest in acquiring the incentive, however this should have been non-differential between exposure groups. As an observational study, the outcomes may have been the result of variables unrelated to the nature of the exposure.

Despite piloting of the knowledge questions in the first CiP-CO questionnaire with clinicians, an expert review of this thesis following analysis and write-up established that scenarios 1 and 2 in the knowledge questions (Table 7-1) provided insufficient information for participants to accurately arrive at the correct responses (Chen ZE [Researcher, FSRH CEU] 2019, oral communication, 26th April). Participants were not provided with information regarding the fictional characters' pill use in the 7 days prior to their missed pills, thus these questions have subsequently been considered invalid. Whilst reassuring that reanalysis of the data with these questions excluded from the total knowledge scores maintained the finding that there was not a statistically significant difference between the mean knowledge scores for the online group compared to the other services group, it remains a limitation of the knowledge element of the CiP-CO study that these questions were not refined or excluded prior to data collection.

Both quantitative studies used IMD, which is a useful and readily available indicator of deprivation, but one which is limited as it relates only to the area in which the service-user lives, rather than to the status of the individual. This limitation is highly pertinent within this research context as a relatively central location in London with a very socioeconomically mixed population with households in close proximity to one another. Unlike Chapter 5, the CiP-CO study had questionnaire data sources so collected more data on sociodemographic background information with variables on education level and employment status in addition to IMD quintile, age and ethnicity. However, this information could still be considered limited in terms of capturing a comprehensive understanding of SES, with no information on job role or income level. However, it was also important that the questionnaires struck a balance between comprehensive collection of data and speed of completion in order to minimise participants becoming fatigued or abandoning them prematurely.

The quantitative methods employed in chapters 5, 6 and 7 did not have the sample size to present findings according to sub-categories of ethnic groups. This limits the interpretation of the findings related to ethnicity and the usefulness of these findings within the ethnically diverse population of Lambeth and Southwark. The findings also fail to transcend the objective/subjective dichotomy advocated by Bourdieu, providing little insight into how and why ethnicity has influenced the contraceptive practice in this thesis.

8.3.3 Challenges, Setbacks and Related Limitations

This PhD commenced in October 2014, shortly after the publication of Lambeth and Southwark's 2014-18 sexual health strategy (162). In this strategy SH:24 is described as a service that will "expand access to clinical services: contraception and diagnosis and management of sexually transmitted infection via a web based service (24 hours a day) linked to telephone and specialist clinic support". Whilst giving an overarching aim of the intervention and how it might operate, the specifics of the service, particularly with regard to the contraceptive element, were largely unknown. SH:24 used a responsive and iterative design process. Reflecting this, the intended elements of the contraceptive service were uncertain throughout the initial planning phase of this PhD, which is apparent in the design of the ToC study in Chapter 4.

Until early 2016, the service was intended to launch with EC provision involving access to LNG or UPA, most likely via home delivery. To reflect this, the original plans for this thesis (as submitted as part of my final upgrade thesis for transfer from MPhil to PhD and oral examination which took place in September 2015) involved evaluation of this intended online EC service. The protocols for these studies can be seen in Appendices A and B. Due to shifts in commissioning priorities in the boroughs, this service input was postponed, and the development of a service providing access to contraceptive information and supplies of OCPs became the new focus. Thus, fifteen months into the start of the PhD process, new study

protocols had to be written, ethical approval gained, and revised plans implemented, leaving reduced time for conducting the research.

These delays had the biggest impact on the CiP-CO study. There was limited time available for recruitment; furthermore, the pace of recruitment was slower than had been anticipated. It was therefore decided to extract the data from participants who had been recruited prior to the end of 2017 so that follow-up procedures could be completed and to enable sufficient time for analysis and write-up prior to the thesis final submission deadline. This, in combination with the need to remove participants whose eligibility criteria could not be verified and the higher than expected losses to follow-up, all contributed to the final dataset available for analysis being far less than specified by the original sample size calculation (section 6.5.5).

There were several reasons for lower than expected recruitment rates which differed according to the study site. Recruitment from the online service had to be delayed due to a later than expected launch. Following this, uptake of online OCPs was initially slower among the target population than required to meet recruitment targets. It also took some time to refine the recruitment process as there was no precedent in the literature for recruiting participants entirely remotely from this type of online platform, via links to a study website. Unlike recruitment in some of the community clinic sites, recruitment from the online service did not have the benefit of immediate discussion with a researcher which may have resulted in online and text recruitment messages being ignored or misunderstood.

More personalised, direct recruitment by researchers positioned in clinics was a relatively successful strategy in the other services group. However, this was a resource intensive endeavour and inconsistently applied as it depended on the availability of researchers and of rooms in clinics for private communication with prospective participants. It was also highly dependent on referrals from non-research staff within sites, which varied according to the extent that they felt motivated, encouraged, well-informed and able to prioritise this among their myriad tasks. Recruitment was largely unsuccessful in general practices as it was not possible to position researchers within these sites and staff not directly related to the research did not prioritise referrals to the study. In order to expand recruitment beyond the larger community clinics to include a range of services available to Lambeth and Southwark residents, online recruitment via social media sites, Facebook and Instagram was temporarily utilised. However, this strategy was problematic due to the narrow eligibility criteria. Those that did sign up needed to have their eligibility verified at the service they named for their first OCP prescription and several had to be removed from the study due to missing data, no record of attendance or failure to meet all stated eligibility criteria when records were checked. The offer of cash incentives may have encouraged illegitimate self-assessment of the eligibility criteria, particularly when recruiting via remote platforms.

Over time, the CiP-CO recruitment procedure was refined, with the termination of recruitment via social media sites, increased texting to encourage uptake among online OCP users and

streamlining of the recruitment in other services to focus on clinics with the most uptake and where researchers could be stationed at regular intervals. Whilst time constraints prevented the analyses within this thesis benefiting from a larger study population, it is promising that such developments have occurred and should lead to greater methodological strength in future publications.

8.4 Findings in relation to conceptual model and theoretical framework

8.4.1 Overarching Theoretical Framework

Integral to the framework were Bourdieu's concepts of habitus, capital and field as the drivers of practice. Chapter 5 identified those who accessed the online service during its initial 15 months according to age, ethnic group and IMD quintile. This provided an indication of the sociodemographic homogeneity in the practice of online access to OCPs that could be a product of the unifying force of habitus and the tendency for capital accumulation within social groups. The lack of ethnic diversity among those accessing the service and the association between being of black, Asian or mixed ethnicity with lower odds of repeat use is consistent with ethnicity as a form of habitus. Whilst this finding provides only a limited indication of the role of ethnicity, the Bourdieusian lens is a useful way to consider its possible implications. It helps to avoid reductive discussions of ethnicity in which differences are viewed as purely cultural, by positioning ethnic differences within wider societal power relations and establishing habitus as relationally bound to capital in its different forms, including that which is economic, social as well as cultural. Ethnicity, as with other social groupings like age, are inherently complex and dynamic, affecting dispositions and opportunities within specific fields. The unequal distribution of capital and the reinforcing power of habitus has resulted in persistent health inequalities in outcomes relating to effective use of contraception which the online service seems unlikely to overcome and could have the potential to exacerbate. Therefore, further inquiry of the subjective is needed to understand the possible barriers to online contraceptive practice, or indeed contraceptive practice in general, which may be experienced by BAME groups.

Viewing the cohort study using this framework gave credence to the theoretical position that the intervention could enhance contraceptive practice with the service rating scores giving some insight into the possible reasons for this. The online service scored more highly than other services in the domains of convenience, communication and speed of access to OCPs. Chapter 3 considered the deployment of capital within physical contraceptive services, not just during the consultation but also in overcoming the challenges of acquiring an appointment and getting to a service. The online service does not require this type of capital which may be why it was considered both convenient and speedy and could partially explain its association with short-term OCP continuation. With regard to communication, it could be that supportive provider contact beyond the consultation via text messaging could help to account for the complexities of contraceptive decision-making that extend into everyday life, particularly for methods like OCPs which require daily adherence, thus contributing to effective contraceptive practice. Basic OCP

knowledge was considered a form of capital, enabling safe and effective OCP use. There was very little difference in these outcomes between the online group and other services group, suggesting that there could be parity in the effectiveness of conveying capital in patient-provider interactions whether they are conducted digitally and remotely or face-to-face.

The Bourdieusian lens was also useful in recognising the limitations of the CiP-CO study, which was observational, meaning that the results could have been due to variables unrelated to the nature of the exposure, which in this case was the type of service. Thus, positive findings in the online group could have reflected the service-users' habitus and pre-existing capital rather than being purely related to the quality and nature of the online service and its interactions with the participants. The online group had a smaller proportion reporting use of EC in the past year and a significantly smaller proportion of smokers compared to the other services group, suggesting that the online service could attract those of a more risk-averse habitus. There was also a statistically significant difference in the proportion of online users who stated that they were likely to take the OCPs prescribed, suggesting that online contraception may be sought out by those with greater agency in their acquisition of OCPs and motivation to comply and continue with the method in their daily practice.

Some of the empirical findings related to themes and concepts in both the overarching theoretical approach and the ToC conceptual model, highlighting the ways in which they complemented one another. The concept of habitus, as an acquired system of dispositions that reflect past experiences, traditions and habits that generate and organise how people act and think in accordance with the social context, overlapped with the stakeholders' assumption that access and effective use of the online service would be contingent upon the circumstances, perceptions and characteristics of the individual. Interestingly, ethnicity, which was the only sociodemographic variable to be associated with repeat use of the online service, was not mentioned specifically by stakeholders, with age being more of the focus, perhaps reflecting the professional positions and background of the ToC study participants. The theoretical framework was useful in unpicking the concept of youth which was discussed frequently by the stakeholders; relating this to generational divisions in familiarity with online access and capital relevant to online behaviour accumulating within younger age groups.

Another area of overlap was in positioning online access within the wider landscape of contraceptive provision. In Chapter 3, the nature of habitus and capital required for effective use of the online service was discussed in relative terms to that which is required for effective use of face-to-face providers, with each provider type representing its own field. In addition, for online access to be a structural shift that facilitates greater agency, it was posited that effective access to face-to-face services would also be necessary to ensure standards of choice in type of method and in the nature of the patient-provider interaction. This coincided with the ToC finding which predicted the success of the online service to be dependent on its integration within other services for access to LARC and more supportive care.

8.4.2 Theory of Change Conceptual Model

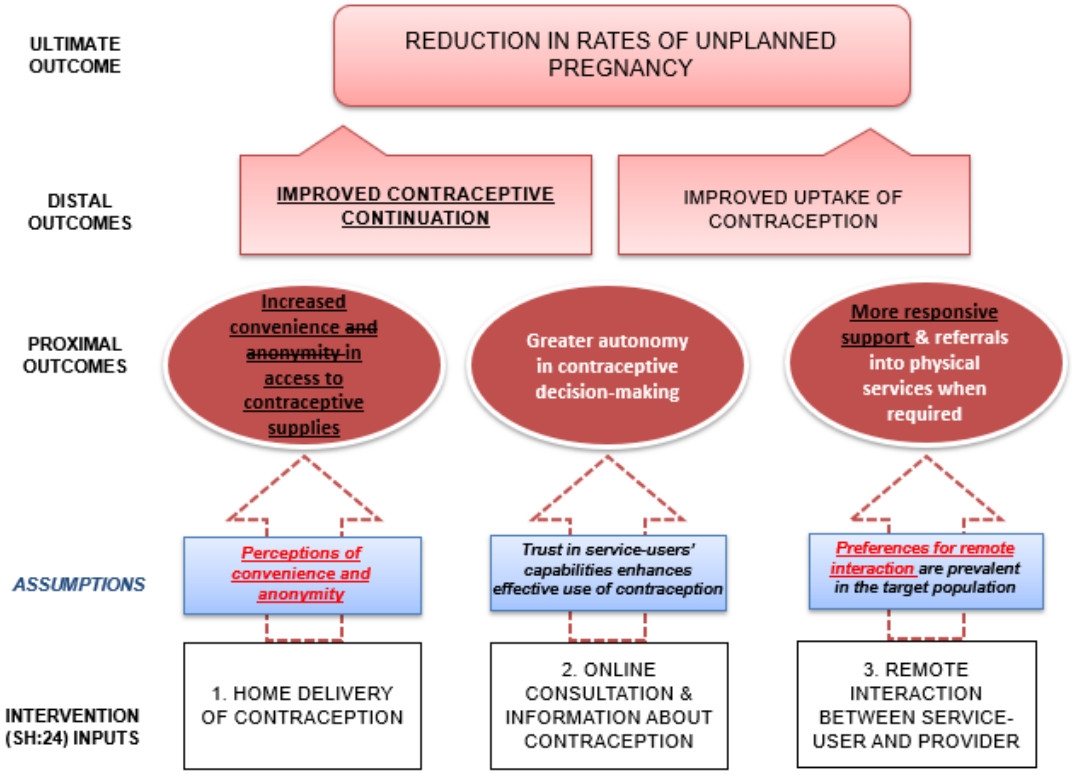


Figure 8-1 Elements of the Theory of Change Conceptual Model which were Tested in the Thesis

Figure 8-1 depicts a return to the ToC conceptual model from Chapter 4 with the areas that were specifically considered in this thesis highlighted in red and outcomes for which an evidence base was established highlighted in black and, where not supported, struck through with a solid line. The CiP-CO study findings suggested an association between online contraception and OCP continuation. Participants who used the online service in the cohort study rated their contraceptive service more highly in the areas of convenience and speed, which attests that these qualities may be integral to positive processes of change. The online service was rated highly in terms of communication, with participants indicating appreciation of the text messages in their free text responses. There were no differences in how the online service and other services were rated in terms of privacy and no mentions of privacy or anonymity in free text responses, contradicting the prediction in the ToC model that online access would be perceived as enhancing anonymity.

Several elements of the ToC model were untested and are therefore not underlined in Figure 8-1. It was not possible to explore contraceptive uptake or to power the CiP-CO study to detect a difference in the outcome of unplanned pregnancy between the two groups within the time and resource constraints of this thesis. Meanwhile, there were aspects of the model which were not explicitly tested but were tangentially explored or touched upon via related lines of investigation.

Whether the online service effectively referred people to physical services was not investigated. The components of the service as evaluated for this thesis did not include any specific referral features, however, it is likely that such advice was provided by SH:24's clinical staff during remote communication with patients requiring advice or services that could not be provided online. The assumption that trust in service-users' capabilities would enhance effective use of contraception and lead to greater autonomy in contraceptive decision-making was also not explicitly studied. However, this was connected to the knowledge element of the CiP-CO study, with the knowledge questions designed to test the capabilities of online service-users to take on information in a more autonomous fashion than in a face-to-face setting. Those accessing online contraception and those attending face-to-face services scored similarly on the OCP knowledge questions which suggests that stakeholder concerns about the risk of online users being unable to safely and effectively take on contraceptive information from an online source may have been mitigated by the quality and accessibility of information delivery. Although this could have been reflective of differences between the two groups which were unrelated to the nature of the exposure.

It is also important to consider the extent to which the findings of the thesis supported the more nuanced findings contained in the narrative that accompanied the ToC model in Chapter 4. The OCP ordering service did not cater to those aged under 18 years, which may be considered a suitably cautious decision given the concerns of stakeholders in the ToC study for younger users to be able to safely and appropriately engage in more autonomous access. However, this, in addition to the finding that BAME groups are less likely to repeatedly order online OCPs, support assumptions in the ToC study that not all groups in the target population are likely to effectively engage with the online service and therefore physical services should remain a priority area for research, investment and development. It was also mentioned by stakeholders that the online service could limit choice of access to LARC methods if it was not well integrated in the wider landscape of contraceptive provision. It was not known at the time of data collection for this study that the service would provide only one brand of COCs and POPs (although information on all contraceptive methods are contained in the information pages (Appendix C)). This further compounds the need for online contraception to be seen as one choice of access among a range of providers.

8.5 Implications

8.5.1 Implications for Practice

This thesis presents the first research on the impact of a complex, online contraceptive service including free to access OCPs delivered to the home. These findings have direct implications for the ongoing design and development of the service and for the LAs in these boroughs in their consideration of continued investment into this service as part of their SRH strategy. These results are also important on a wider scale as the promotion of social enterprises and use of

technological innovation to increase access to contraception has been included in national strategies.

Part of the rationale for a ToC approach to evaluation development was in its positioning of the researchers as active stakeholders in the intervention and its capacity to be responsive to the agile and iterative approach to design adopted by SH:24. The findings in thesis are therefore intended to have value in shaping the direction of the ongoing design and refinement of the online contraception service. Description and analysis of the service's routinely collected data provide a useful indication of those in the target population who have preferences for the service and who are likely to use it repeatedly. This identifies those in the target population that may require further research to ensure the service can meet their needs. The service was not widely advertised or promoted during the time frames of this thesis, so it recommended that such activities should be prioritised and targeted toward particular groups, such as BAME groups, to ensure there is widespread awareness in the target population. The service rating and knowledge scores in Chapter 7 indicate both where online contraception is performing well and where it could improve. The free-text data specifically mentioned appreciation for the text message communication. These results, in addition to the review of the literature on remote and digital contraceptive interventions and theoretical work in Chapter 3, suggest that the online service should further capitalise on this route to enhance the conveyance of capital for effective contraceptive practice.

The finding that short-term OCP continuation was significantly greater in the online group when compared to those accessing other services, provides reassuring initial evidence that Lambeth and Southwark LAs could see positive public health outcomes as a result of investment in this novel mode of service delivery. That the online group had OCP knowledge of a similar standard to those attending face-to-face services is also reassuring about the capacity for service-users to understand and interpret complex, contraceptive information in a remote and digitised format. These results are also encouraging on a wider scale, as the promotion of social enterprises and use of technological innovation to increase access to contraception has been included in national strategies. However, it is important to acknowledge outcomes relating to knowledge among the online service group may have been affected by their knowledge prior to use of the online service and that, as a group who took up the service during its early stage of availability, they may not reflect the general population. Furthermore, it is also necessary to address the concern that the online service in its current form may not have the capacity to meet the needs of some at risk groups in the boroughs.

BAME groups were found to be less likely to repeat order their OCPs from the online service relative to those of white ethnicity. It was also found that just 9.0% of online users were aged 16-19 years, most probably due to the age restriction of 18 years and over that was implemented by the service. This can be situated within a broader picture of poorer SRH outcomes for ethnic minority groups and younger women. Among the pregnancies occurring in adolescents in England, many are reportedly unplanned and over half result in abortions (190).

Sexually active women from minority ethnic groups are less likely than white women to use effective methods of contraception (8) and a study on OCP continuation within a 12-month follow up period found that black women were more likely to discontinue (adjusted HR 1.21, 95% CI 1.02 – 1.44) (307). It has been discussed in section 2.9.1, that the black ethnic population is substantial in Lambeth and Southwark, relative to other boroughs in London and the UK (190). In both boroughs, repeat abortions are more common among black African and black Caribbean women than in other ethnic groups (189). It is also possible that inequalities pertaining to age and ethnicity could intersect in the target population as in Lambeth, 80% of 10 – 19 year olds describe themselves as non-white British, compared to 50% of 20 – 29 year olds (47).

Whilst the findings in Chapter 5 revealed some concerns about the capacity for the online service to meet the contraceptive needs of adolescents and BAME groups, it also reported that most service-users were residents of areas in the most deprived IMD quintiles. Future commissioning decisions in Lambeth and Southwark should take note of the capacity of the online service to attract service-users that reflect the target population in terms of this measure of socioeconomic deprivation. This finding is also indicative that the online service could meet the needs of an at risk group as it has been reported that socioeconomic characteristics are determinants of contraceptive use operating at the individual and area level with area disadvantage associated with lower likelihood of use (54). Further investigation is required to understand the socioeconomic status of individual service-users rather than relying on IMD measures alone.

The study in Chapter 5 did not compare outcomes to other services so it is unknown whether community clinics, GPs or other providers in Lambeth and Southwark have similar or different issues with attracting BAME and younger service-users and encouraging their repeat use compared to the online service. However, French et al.'s (2017) analysis of NATSAL-3 data suggested that community clinics are more commonly used by women in living in urban areas, women living in more deprived areas and women in black and other ethnic minority groups (70). Furthermore, this study found that general practice was used by fewer women aged 16-17 years compared to older age groups and use of community clinics declined with increasing age. Future commissioning decisions should take into account the potential pitfalls of strategies that fail to prioritise providers that are frequently accessed by BAME groups and younger women. Continued disinvestment in contraceptive provision by community clinics and other physical providers may have the biggest impact on the groups most at risk of poor reproductive outcomes in Lambeth and Southwark.

The ToC conceptual model and narrative stressed that many of the positive processes of change generated by the intervention are judged to be contingent on the extent to which the service is embedded within existing provision. This was to ensure access to more complex care when required and to maintain choice of all contraceptive methods, especially LARC. Whilst the quantitative studies in this thesis did not explicitly address this issue in their stated outcomes,

some secondary outcomes in the CiP-CO study indicated that the OCP users did switch methods and services during the study period. The risk difference between the online contraception and other services group declined from 20.44 (2.10 – 38.48) (p=0.029) when looking at OCP continuation only to a non-statistically significant risk difference of 15.93 (-2.11 – 33.97) (p=0.090) for the secondary outcome of continuation of any effective method (including OCPs). This was due to a greater proportion of participants (6/40 = 15.0%) from the other services group switching to other effective methods including IUDs, vaginal rings and implants. There was also some switching to alternative services for participants' next contraceptive prescription (15.4% in the online group and 17.5% in the other services group). Whilst the main aim of this thesis has been to evaluate the online service, the importance of choice cannot be separated from any assessment of contraceptive practice. These findings from the CiP-CO study, in addition to the background literature in Chapter 2 and the theoretical underpinnings outlined in Chapters 3 and 4, all emphasise that both choice of method and choice of provider remain fundamental indicators of quality in contraceptive provision.

The service rating outcomes in Chapter 7 are of value to understand areas for improvement for the community clinics and GPs used by participants in the other services group. These reiterate what is already known about the long waiting times in walk-in services creating barriers to access and bolster the case for increased investment in these services to address these issues. This thesis has not explored whether online contraceptive services can offer a cost-effective solution to issues of demand outstripping capacity in face-to-face provision. However, it is unlikely that online services alone can address the contraceptive needs of a population, particularly that of Lambeth and Southwark, which bears a disproportionate burden of poor SRH outcomes. The success of multi-stranded strategies that have encompassed increased funding for LARC methods and policy interventions discussed in section 2.7, demonstrate that unplanned pregnancy is a complex issue requiring substantial investment and multi-sectoral commitment to long-term solutions.

8.5.2 Implications for Research

Application of Bourdieu's Theory of Practice for the theoretical framework of this thesis and use of Bourdieu's reflexive sociology paradigm have demonstrated that more abstract, sociological approaches do not have to be incompatible with contraceptive health services research, particularly where mixed methods are employed. The theoretical framework complemented the use of the theory of change approach, allowing the thesis to straddle both a process evaluation line of inquiry, more localised in focus, in addition to a public health impact line of inquiry that contextualised findings within wider societal hierarchies and inequalities. However, there was tension between the more abstract and fluid Bourdieusian concepts and the more pragmatic, realist ToC approach, which were not fully resolved in this thesis. The ToC generated hypotheses and shaped study designs which did not sufficiently account for the subjective in the target population's response to the online service. When viewed through a Bourdieusian lens, it was apparent that data was limited in capturing the highly nuanced concepts of habitus, capital

and field. Nonetheless, these frameworks have established the knowledge base for this novel service. These can be refined and developed in order for the knowledge base to expand for broader theorising in this new era of remote and online health.

This thesis has highlighted the value of using a diverse range of data sources and a mixed methods approach to evaluate a service, particularly one which is novel and requires both exploratory and experimental research. Chapter 4 used three qualitative data sources; the original programme funding application, secondary transcripts of interviews from a previous study and supplementary in-depth interviews. Chapter 5 demonstrated the value of routinely-collected data for an initial picture of use of the new service. Both studies provided useful exploratory findings to generate further questions for the evaluation and provided the groundwork for development of the CiP-CO study.

The CiP-CO study employed both objective and self-reported data. The self-reported questionnaires were developed through careful consideration of the background literature and use of the conceptual model and theoretical framework, acknowledging the range of factors that can influence contraceptive decision-making. They were also tested with contraceptive healthcare professionals and prospective participants. Furthermore, free-text responses indicated that they were well received by participants and that the knowledge section was found to be very useful for the new OCP users (Appendix S). Participants suggested that the wording, structure and delivery of the online questionnaires was of a good quality and appreciated the opportunity to test their contraceptive knowledge. Future research in this area could benefit from the design and delivery of these questionnaires.

The limitations, particularly in terms of recruitment, were extensive for the CiP-CO study, as detailed in Chapters 6 and 7 and in section 8.3. These have implications for future research in this field and for studies utilising online recruitment and sign-up procedures. It is recommended that observational research with strict eligibility criteria based on health service-use avoids social media recruitment and focuses resources on direct recruitment from the relevant services. The rate of recruitment, particularly from the online service, was over-estimated. Research into innovative services may benefit from more prudent recruitment targets, incorporating longer recruitment periods into study protocols to account for challenges in establishing alternative health delivery approaches and delays in uptake among the target population.

Finally, as outlined in Chapter 2, this era of contraceptive provision, and NHS purchasing more widely, can be characterised by the increasing prominence of technological innovation and social enterprise procurement. Online interventions from social enterprises like SH:24 are likely to increase in prevalence within the current policy and commissioning environment. Researchers and evaluators of these interventions must keep pace with the flexibility of social enterprise providers to develop and alter their service in response to changing priorities of

commissioners and evolving service-user demands. The original research plans for this thesis had to be swiftly reconfigured due to a sudden alteration in plans for delivery. Stages integral to the academic research process such as study design, ethical approval and publication can be time-consuming and can result in services being commissioned and implemented prior to the availability of a robust evidence-base to inform decision-making. As health care technology continues to develop and expand and NHS providers continue to search for more cost-effective, innovative solutions to rising costs and growing demand, there is an urgent need to address this time lag. The methodological approaches employed in this thesis, both those that were successful and those that were problematic, provide useful learning for future research in this emerging field.

8.6 Directions for Future Research

If short-term OCP continuation is considered a kind of contraceptive practice, then ethnicity may be integral to the shaping of this practice, borne of the habitus and relationally bound with capital and field. Further qualitative work is recommended to gain deeper insight into ethnicity as habitus and its role in contraceptive decision-making. Overall, the findings in this thesis have not transcended the subjective/objective dichotomy as centralised in Bourdieu's ontological approach. Understanding contraceptive practice as affected by online provision requires a deeper consideration of the subjective. In addition to specific consideration of ethnicity, further in-depth interviews are recommended, with a purposive sample of contraceptive users and non-users, discussing their responses to the online service and reasons for non-use, use and repeat use.

TDE literature recommends that a ToC model is refined upon completion of an evaluation on the basis of what inputs were actually implemented by the intervention and their effects (293, 294). Whilst this chapter has related findings to the conceptual model and highlighted the areas that have been investigated (Figure 8-1), it is also recommended that further qualitative work is conducted to discuss the effects of the service with stakeholders to generate an updated ToC model. This could investigate how the online service has been perceived by staff in SRH services in Lambeth and Southwark, by commissioners and by those who have designed and implemented the service. This could also include interviews with CiP-CO study participants and other online service-users.

The ToC study was hypothesis-generating, indicating several avenues for research which could not all be pursued within the confines of this thesis, as shown in Figure 8-1. The potential for online contraception to improve uptake of contraception is an important area to explore. Further research in this area would require data from participants not already accessing contraception and who are likely to be experiencing unmet need. The qualitative findings contain predictions from stakeholders that the speed and convenience of the intervention in addition to the use of remote communication, may appeal to members of the population who experience barriers to access at general practice and community clinics. An RCT design is recommended, such as

that employed by Wilson et al. (2018) to test the effectiveness of the online STI testing and results element of the SH:24 service (193), which exposed participants to promotional information pertaining to either the online service (intervention arm) or existing, face-to-face services (control arm). This would permit the testing of the hypothesis that online contraception could increase uptake of contraception among a population with unmet need. Similar to the recruitment procedures employed by Wilson et al. (2018), such a study could also prioritise community recruitment that targets those at high risk of ineffective contraceptive practice and unplanned pregnancy.

The methods employed in Chapter 5 were useful to explore the initial routinely collected data from the intervention. It is recommended that the analysis procedure is repeated on a larger sample size, when the online intervention has been more widely and frequently used. This would enable regression analysis using ethnicity data for sub-categories rather than the broad ONS groups used in this chapter. It would also be useful to compare outcomes to OCP users accessing community clinics and general practice in Lambeth and Southwark to detect differences in sociodemographic characteristics and patterns of use between intervention users and those accessing other providers in the area.

The use of an observational study design to compare OCP continuation between users of the online service and users of other services had its merits as outlined in section 8.3.1. However, to remove the influence of potentially confounding factors not captured in the questionnaires, an RCT is recommended to provide conclusive evidence for the effectiveness of the intervention of online contraception to improve continuation in this population. It is also recommended that future studies extend the follow-up period to establish evidence for long-term continuation. Ideally, future research would have sufficient power to detect differences in the outcome of unplanned pregnancy. This could also examine whether the effect of the online provision differs according to sociodemographic characteristics, with a specific focus on whether outcomes differ among different ethnic groups.

Chapter 7 analysed the components of the CiP-CO questionnaire which tested participants on their OCP knowledge and asked them to rate their OCP service across domains derived from the theory of change study. Embedding these elements within the larger questionnaire for the fulfilment of secondary objectives necessitated an economical approach to length and number of questions. Further research could be focused on these specific areas using questionnaires designed to fulfil these outcomes alone. More complex, rigorously validated questionnaires could be developed for further understanding of each aspect of service quality and OCP knowledge, with enough measures to cover the various interpretations of each of the domains of service quality and a more comprehensive test of all aspects of knowledge. In addition, following the discovery of concerns with the validity of three of the knowledge questions (see section 7.7.2), it is recommended that care is taken to pilot a larger sample of experts to ensure accuracy of such questions prior to data collection.

The free text responses gave an indication of some of the nuances in these interpretations of service quality. However, this opportunity for participants to share their feedback to an open-ended question about services came only once and very near to the end of the final questionnaire, by which point participants may have been fatigued or dropped out. In addition, the qualitative analysis was deductive using the framework for quality determined a priori. The richness of the small amount of qualitative data available suggests that further research, involving in-depth interviews with OCP users, would facilitate a more inductive analysis of perceptions of the different services, which may reveal topics beyond those resulting from the theory of change study (Chapter 4).

Finally, it is recommended that these suggestions for future research in online contraception benefit from awareness of the methodological challenges encountered within this thesis. Evaluating a real-life, commissioned, social enterprise-delivered health service requires responsive and timely research design and implementation. The difficulties and delays of responding to the sudden alteration in the online service design from being EC-led to focusing on OCP delivery, had ramifications for the entirety of the thesis, including in the execution of research strategies in the CiP-CO study. Whilst the service under investigation in this thesis was able to deliver contraceptive provision of demonstrably good quality to its users through an entirely remote and digitised platform, recruitment procedures were less effectively delivered in this way. Recruitment was more successful when delivered by researchers who could explain the study directly to prospective participants and work with providers to identify potentially eligible participants, both in face-to-face services and online. However, once recruited, the online format and structure of the questionnaires and their delivery via text message were straight-forward to organise and carry out and well-received by participants. As with contraceptive provision itself, methodology which employs a combination of online and automated text messaging communication approaches, in addition to more supportive interaction, are likely to maximise recruitment and follow-up for higher-quality research.

8.7 Conclusions

These are the first empirical findings on free to access, online contraception and indicate its potential to improve short-term continuation of OCPs, convey relevant information to a similar standard as face-to-face providers and receive high ratings in areas of communication, convenience and speed. Contraceptive practice is unique among other areas of health, requiring interactions with providers in which there is emphasis on patient agency to choose a method that will suit the routinised, day-to-day behaviour of the individual. Online contraception is a fundamental structural shift in provision, however, this is only likely to expand choice when embedded within the range of existing services. Ongoing investment and development of both online and face-to-face provision are recommended to ensure that contraceptive choice is enhanced rather than reduced.

Whilst the strong theoretical and conceptual underpinnings have facilitated the gathering of a useful, foundational evidence-base, there have been challenges in keeping pace with the rapid developments of the service and difficulties in executing online and remote recruitment strategies. This thesis is therefore a contribution to the field in terms of its findings, but also in improving the methodology for future research. Further qualitative enquiry is required to better understand the influence of habitus and capital on the use of online contraception with particular focus on the role of ethnicity. Further quantitative research using a larger study population and analysis of longer-term outcomes, including unplanned pregnancy, are urgently required to inform local and national commissioning decisions. Online contraception and similar technological innovations in healthcare delivery are likely to proliferate locally and nationally in the current policy context, therefore, it is vital that sound epidemiological research is at the forefront of this rapid pace of change.

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Appendix A. Emergency Contraception Protocol

MEASURING THE FEASIBILITY AND ACCEPTABILITY OF AN INTERNET-BASED EMERGENCY CONTRACEPTION SERVICE

PROTOCOL Version Eight 22.10.15

Project Title

Measuring the feasibility and acceptability of an internet-based emergency contraception service.

Research Aims & Objectives

This study aims to describe the feasibility and acceptability of an internet-based EC service through satisfying the following objectives:

- To report the feasibility of the internet-based service to deliver timely EC by measuring the length of time elapsed from self-identified risk of pregnancy or unprotected sexual intercourse (UPSI) to delivery of EC in days using routinely collected data.
- To describe time elapsed from UPSI to EC delivery using routine data obtained from existing EC services in Lambeth and Southwark over the same time period for comparison to internet-based EC.
- To report the time that EC is taken after delivery by users of the internet-based service who consent to follow-up via telephone questionnaire.
- To describe the service user profile of those accessing the internet-based EC service.
- To describe the user acceptability of the internet-based EC service via the telephone questionnaire.

Background

Unintended Pregnancy - The Global Context

An unintended pregnancy is that which is reported to have been unwanted or mistimed (51). It is a major public health concern due to its ubiquity (50), its negative impact on women's health (2) and its disproportionate effect on women in lower socioeconomic groups (344). It is also a financial strain on the resources of national health systems (53, 345). Globally, of the 208 million pregnancies that occurred in 2008, approximately 41% were unintended, which includes 33 million unplanned births, 41 million induced abortions and 11 million miscarriages (50).

The average global birth rate among 15 to 19 year olds is 49 per 1000 (346). Mistimed pregnancies are particularly common amongst adolescent and young adult women (51). The consequences of unintended pregnancy for this age group can include the loss of educational opportunities and societal marginalization (50). Teenage pregnancy is often simultaneously a marker of socioeconomic disadvantage and a cause of further disadvantage and negative health outcomes (347).

Unintended Pregnancy - The National Context

In 2010, there were an estimated 225 600 unintended pregnancies in England directly costing the NHS £193 200 000 (53). Estimates suggest that approximately 16% of all pregnancies in 2011 were unplanned (1). The age-standardised abortion rate was 15.9 per 1000 resident

women aged 15-44 in England and Wales in 2013 (348). This is the lowest recorded rate for 16 years. However, unintended pregnancy is still a public health priority (21). The UK adolescent birth rate remains high compared to other developed countries at 9.2 births per 1000 women aged 15-17 (349). There is a 6-fold difference in adolescent conception and birth rates between the poorest and most affluent areas in England (350) and access to contraceptive services is most problematic for people in disadvantaged communities (351).

The majority of women (75%) who are under 50 years of age in Great Britain use at least one method of contraception (352). The National Institute for Health and Care Excellence (NICE) outlines that a commitment to the continued improvement of contraceptive services is necessary to not only further reduce unplanned pregnancies, but also reduce inequalities and improve NHS spending efficiencies (353). Contraceptive services include access to emergency contraception (EC). This has been expanded through patient group directions (PGDs), which allow suitably qualified nurses and pharmacists to dispense free oral EC to young women without prescription (354).

Emergency Contraception

EC is a vital and effective contraceptive option for women and the only method that can be used after unprotected sexual intercourse (UPSI) or sexual assault or to compensate for the failure of other forms of contraception. There are three EC methods that can be used in the UK: 1.5mg single oral dose levonorgestrel (LNG); 30mg single oral dose of ulipristal acetate (UPA) and the copper-bearing intrauterine device (Cu-IUD) (355) (Table 1).

Table 1: Summary of Methods of Emergency Contraception in The United Kingdom. Information is adapted from Faculty of Sexual & Reproductive Healthcare Clinical Effectiveness Unit Guidance Emergency Contraception August 2011 (Updated January 2012), unless otherwise referenced within the table.

Emergency Contraception (EC)	**Mechanism of action**	**Licensed Time Frame**	**Advantages**	**Disadvantages**
Levonorgestrel (LNG)	A progestogen hormone that prevents follicular rupture and ovulation	Within 3 days post unprotected sexual intercourse (UPSI) or contraceptive failure	1. Easily accessible from a range of providers 2. No medical contraindications 3. Can be used more than once in the same cycle	1. Ineffective once the luteal hormone has started to rise 2. Subject to the inaccuracies of self-reported cycle information (140) 3. Possible minor side-effects, e.g. headache, nausea and altered bleeding patterns
Ulipristal acetate (UPA)	A progesterone receptor modulator that prevents follicular rupture and ovulation	Within 5 days post UPSI or contraceptive failure	1. Can be used until just after the rise in luteal hormone so the window of opportunity for pregnancy prevention is extended (141, 142) 2. Limited accessibility as all products are prescription only medication	1. Medical contraindications include pregnancy and severe uncontrolled asthma 2. Possible interaction between UPA and progestogen-containing contraception 3. Not advisable to use UPA with liver enzyme-inducing drugs. 4. Possible minor side-effects, e.g. headache, nausea and altered bleeding patterns
Copper-bearing intrauterine device (Cu-IUD)	Prevents fertilisation and effects the uterine fluid and endometrium (143)	Within 5 days post first UPSI in a cycle or within 5 days from the earliest estimated date of ovulation	1. Can provide regular, effective contraception for up to 10 years 2. Highly effective to prevent pregnancy even post-ovulation	1. Requires an invasive procedure by a trained healthcare professional 2. Contraindications include untreated sexually transmitted infections or pelvic infections 3. Possible complications once fitted, e.g. rejection by the womb 4. Possible side-effects if used as contraception e.g. vaginal bleeding and pain

Results from a recent systematic review give the emergency Cu-IUD a failure rate of just 0.09%, (356). However, fitting is an invasive procedure that must be conducted by a trained healthcare professional within a clinical setting such as General Practice (GP) or Sexual and Reproductive Health (SRH) services. Oral forms of EC are frequently considered to be more acceptable and convenient and are more commonly used (352). Table 3 provides the results of randomised trials and a meta-analysis of UPA versus LNG and demonstrates that both oral forms of EC are highly effective. The meta-analysis suggests that UPA may be more effective than LNG in all time periods up to 120 hours post-UPSI although this was non-significant in the individual trials (357, 358). LNG is ineffective once LH has started to rise (359) and UPA is ineffective in delaying follicular rupture once LH has peaked (360). The two primary factors

that healthcare professionals consider when EC is requested are the timing of all episodes of UPSI in the current cycle and the most likely date of ovulation (355).

Despite the body of evidence indicating EC is a valuable and effective approach to pregnancy prevention for the individual, studies report that increasing access to hormonal EC does not reduce overall pregnancy rates (127, 128) or abortion rates (129, 130) or unintended pregnancy rates on a population level (131). Non-use of EC is often related to failure to recognise the risk of pregnancy (132), the neglect of perceived risk (133), inconvenience and fear of side-effects (134). Qualitative studies interviewing young women from urban areas also report stigma, personal difficulties in asking for EC, experiences with healthcare professionals and misperceptions about the method as further barriers to EC (135, 136). It may be that the current configuration of EC services are not meeting the needs of all women (137) and that interventions that have sought to increase access have not targeted those most at risk (138, 139).

Table 2: Results of Randomised Trials and Meta-Analysis of Ulipristal Acetate versus Levonorgestrel from Faculty of Sexual & Reproductive Healthcare Clinical Effectiveness Unit Guidance Emergency Contraception August 2011 (Updated January 2012). UPSI, unprotected sexual intercourse; OR, odds ratio; NS, non-significant difference; CI, confidence

Authors	Design	Time since UPSI (hours)	Ulipristal acetate			Levonorgestrel			OR (95% CI)	p
			Exposed (n)	Pregnancies (n)	Rate (%)	Exposed (n)	Pregnancies (n)	Rate (%)		
Creinin et al.(357)	Phase II randomised non-inferiority trial	0-72	773	7	0.9	773	13	1.7	0.50 (0.18-1.24)	0.135 NS
Glasier et al.(358)	Phase II randomised non-inferiority trial	0-120	941	15	1.6	958	25	2.6	0.57 (0.29-1.09)	0.091 NS
Glasier et al.(358)	Meta-analysis	0-24	584	5	0.9	600	15	2.5	0.35 (0.11-0.93)	0.035
		0-72	1617	22	1.4	1625	35	2.2	0.58 (0.33-0.99)	0.046
		0-120	1714	22	1.3	1731	38	2.2	0.55 (0.32-0.93)	0.025

Internet-based Contraception Services

The capacity for existing services to continue to cater for growing demand for contraception is not assured (11). The nature of this demand is also shifting, with technology-mediated models of service delivery pioneered in the private industry, becoming increasingly widespread in healthcare (361). Evidence regarding the public health benefits of online testing for sexually transmitted infections (STIs) is growing (362). In contrast, online services for contraception in the UK remain restricted to the private sector (363, 364) and, where freely available, are limited to information-only or signposting facilities, such as the contraceptive components of the National Health Service's NHS Choices site (365) or My Contraception Tool (36).

Innovation in service delivery via an internet-based system has the potential to overcome many of the barriers that have hindered EC from having a population-level impact by offering a new route of supply to free EC. There is some limited evidence to suggest acceptability of and demand for internet-based sexual and reproductive health services, often citing privacy of access and convenience as advantages of this mode of delivery (164, 342, 366, 367).

Sexual Health 24 (SH:24) aims to expand access to clinical services by providing contraception and diagnosis and management of STIs via an internet-based service linked to telephone and specialist clinic support. The internet-based STI testing and diagnostics component was launched in March 2015 and in December 2015 it will launch access to EC and POP via the same website. SH:24 services are restricted to those aged 16 years and above and residents of the boroughs of Lambeth and Southwark.

Internet-based EC delivery is an untested intervention and therefore, feasibility and acceptability of the service are to date, unmeasured. Timely intake of EC according to the restricted periods of efficacy for individual methods is vital to feasibility. Therefore, this study will measure time from UPSI to EC delivery reported by SH:24 users, which will then be compared to results collected in parallel in face-to-face services. This observational study will focus on establishing whether internet-based EC is a feasible and acceptable service to those who are eligible. It will also provide information about the service users to develop understanding of the demand for online contraceptive services and their capacity to cater to members of the population at high risk of unintended pregnancy.

Research Context

Lambeth and Southwark are adjacent inner London boroughs which are ethnically diverse and densely populated with high levels of deprivation (368, 369). However, there are also pockets of affluence in the boroughs and the high proportion of young people of working age allow for a very economically active population.

The boroughs have rates of abortion, repeat abortion and unintended pregnancy that exceed national averages (368, 369). An analysis of abortions performed by local providers between 2008 and 2013 shows that rates are much higher in those who identify as Black/African/Caribbean/Black British or Other Ethnic Group (162).

The residents of these boroughs have access to a range of services providing free contraception. There are open access, walk-in, integrated SRH services such as Camberwell Sexual Health Centre, as well as community clinics and Brook services. Many people also attend GPs for their contraceptive needs (370). It can be problematic for some people to access these services because of inconvenient opening times, long waiting times and high numbers of people being turned away (9, 11, 371). The comparative speed and convenience of access to pharmacies explains their popularity as access points for EC, with 11784 free EC consultations reported in the boroughs in 2013-14 (372) relative to just 3853 in GPs (370).

The Local Authorities (LAs) in these boroughs are committed to reducing rates of unintended pregnancy and repeat terminations within a context of proposed public health spending cuts in the face of rising clinical activity (162, 373). Part of their strategy is to shift non-complex activity to SH:24 in order to allow SRH and other services to dedicate more time to complex cases.

Methods: Design Strategy & Framework

A retrospective, longitudinal study utilising routine data collected in parallel from the intervention and from existing EC services. Users of the intervention who provide consent after completing online assessment for EC delivery will also be followed up with a telephone questionnaire. This will assess the feasibility of internet-based access to provide timely emergency contraception compared to local pharmacies and clinics.

The acceptability of the internet-based EC service will be measured via additional questions in the telephone questionnaire. This questionnaire will be piloted before use in the study.

Exposure

Exposure is defined as the point of access through which users obtain a method of EC.

The Intervention - internet-based EC (SH:24)

The service will provide 1.5mg single oral dose LNG or 30mg single oral dose UPA from the NHS by logging onto a secure website, completing a risk assessment and ordering EC (free of charge). EC will be dispensed provided the service-user meets the eligibility criteria specified by SH:24. EC will be delivered directly to the service-users' home addresses.

Larger integrated SRH clinics

SRH services in Lambeth and Southwark provide the full complement of EC methods, including a fast-track system to prioritise service-users who require EC.

Pharmacy

1.5mg single oral dose LNG is freely available from community pharmacies for women between 13 and 49 years of age in Lambeth and all women under 30 in Southwark. The main pharmacy provider in each borough will be selected to provide routine data for the study.

Sample Size Calculation

The sample size calculation adapts methods from survival analysis in order to satisfy the primary outcome of time from UPSI to taking EC. This is based on the probability that the subject will experience an event during the course of the study. In survival analysis this is dependent on the pre-determined study duration, however, in this case, the time frame of interest reflects the licenced time frames of the different EC methods. Thus, the sample size is based on the assumption that 98% of people obtaining EC at an SRH clinic will do so within 72 or 120 hours post-UPSI for LNG or UPA/Cu-IUD methods of EC respectively based on a sample of 60 case notes from Camberwell Sexual Health Service.

A predicted hazard ratio of 0.9 would account for a 10% difference in the outcome between the SRH clinic exposure and SH:24. A log rank test comparing two survivor curves (SRH clinic EC-users and SH:24 users) uses the underlying hazard ratio of 0.9 to obtain 90% power and assumes equal distribution between the two groups and an estimated 20% censoring or loss to follow-up. A minimum recruitment of 534 participants (178 per exposure) is estimated to obtain at least 90% power to detect a difference of at least 10% in the proportion obtaining EC within the licensed time frame post-UPSI, based on a two-sided alpha test with a 5% significance level.

It is unknown how many individuals will utilise the internet-based EC service. Data from SH:24 from 1st March to 16th July 2015 reports that of the 2230 service-users completing the online assessment for a postal STI kit, 1377 were female (374). 846 female users also reported

unprotected sexual intercourse within the 5 days preceding the order. From this it is estimated that recruitment will take 2 - 3 months at a rate of approximately 50 - 100 per month.

Data Collection

Data collection will take place in parallel at all three exposures with the prediction that collection from SH:24 is likely to take double the amount of time due to the added necessity of consenting participants.

Inclusion criteria

- Provided with EC during the study period by SH:24 after completion of an online assessment form.
- Provided with EC after consultation with the relevant healthcare professional at Camberwell Sexual Health Service; Streatham Hill Clinic; Lloyd Clinic at Guy's and St. Thomas' Hospital; the biggest pharmacy provider of EC in Lambeth and the biggest pharmacy provider of EC in Southwark.
- Above the age of 16 years old.

Exclusion criteria

- Those who are ineligible for EC at the point of access from which data is collected according to the criteria of the provider, for example, those who have medical contraindications to the EC options available at the service.

Recruitment and consent

Most of the data will be collected via routine sources. The standard consultation for provision of EC will provide the required data and therefore consent will not be necessary for the bulk of the data.

The majority of the routine sources record data electronically, for example all pharmacy data in Lambeth and Southwark is recorded on the Pharmoutcomes electronic database. Camberwell S exual Health Centre currently records most of the consultation on
paper files which will be retrieved, read, anonymised and recorded by a member of the care tea m.

Data Analysis

1. The primary outcome is dealing with time to an event – time from UPSI to delivery of EC. Kaplan-Meier (K-M) curves will be generated for subjects in the three different exposure groups to facilitate comparative analysis. The data collected will be displayed as shown in Table 4. The curve will be shown as step functions – horizontal at all times there is no outcome event with a vertical drop corresponding to the cumulative chance of receiving EC post-UPSI against time in days. Subjects will either have the event of interest or will be censored. This will determine if there are statistically significant differences between the curve distributions of the 3 exposures and if so, which specific exposures differed from each other.

2. A Cox proportional hazards regression model will be used to determine the effect of type of EC service upon the number of days it takes for EC to be delivered post UPSI. The model will enable the identification of which independent variables act as intensifiers and will demonstrate their statistical significance within a 95% confidence interval. This will first require univariate analysis for identification of risk factors to be included in the model by means of chi-squared testing, calculation of relative risk and K-M curves of each variable.
3. Analysis of Survey Data:

   Survey responses will be assigned numerical codes that will enable univariate analysis using descriptive statistics. Likert scales will be combined into indexes for parametric analysis, provided the data is normally distributed.

   The relationship between variables based on nominal levels of management will be examined through cross-tabulation of the variables and bivariate analysis of associations.

   Missing survey data will be imputed, either deductively by comparison to routine data from SH:24 or through use of hierarchical hot-deck imputation procedures.

Outcomes

Primary Outcomes

1. Time to delivery of EC post-UPSI in days for each exposure.

Secondary Outcomes

1. Time to taking EC post UPSI in days per exposure for users of the internet--based EC service.
2. Descriptions of acceptability from users of the internet-based service through use of a Likert scale obtained via a telephone-based questionnaire.

Table 3: Outcome Measures and Methods of Analysis

Outcome	Outcome measure	Method of analysis
1. Primary		
Time to taking EC post-UPSI in days per exposure	Objective (ordinal) for SRH clinics and pharmacies Self-report (ordinal) verified by objective for SH:24	1. Chi-squared test 2. Relative Risk ratios 3. Kaplan-Meier Curves (binary) 4. Cox Proportional Hazards Regression
2. Secondary		
Descriptions of acceptability of the internet-based EC service	Self-report (indexes)	Analysis of Variance

Limitations

This is a feasibility study and is designed to provide initial data on this innovative service as a springboard for further investigation. Data for the primary outcome relies on routine data which can be limited in its reliability, richness and consistency across service providers (375). For example, it is predicted that there will be heterogeneities on demographic data collected from service-users in pharmacies compared to SRH clinics. There can be self-report issues with routine data collection for contraceptive services, particularly around identifying when multiple UPSIs have occurred and dating of menstrual cycles (140).

It is also stressed that the primary outcome seeks information about time to *delivery* of EC across the exposures. The actual time that EC is taken (if it is taken at all) is not being investigated, primarily because it is beyond the scope of the study to determine this. The telephone questionnaire for consenting users of the internet-based service will provide some additional information about potential time delays from delivery of the EC to the participant actually obtaining and taking the pill.

All data from the telephone questionnaire is subject to self-report bias. The outcome of acceptability of internet-based EC is measured via questions in the telephone questionnaire that require Likert scale responses. This scale is subject to three main sources of bias: 1) central tendency bias; 2) acquiescence bias; 3) social desirability bias. Acquiescence bias can be minimised through the inclusion of an equal number of positive and negative statements about the service.

Finally, the questionnaire can only be carried out on participants who consent to follow-up, which may limit how reflective the results are of those seeking internet-based EC in Lambeth and Southwark. A service-user profile containing demographic data will be reported for all those who complete the online consultation on SH:24 during the study period to establish how representative the consenting participants will be of this population.

Ethical issues: consent, access and participants' protection

All participants recruited via SH:24 for follow-up via the telephone questionnaire will be provided with online information about the study and contact details of the study coordinator should they have any further queries.

Participants may request to withdraw from the study at any stage and will be reminded of this just prior to the initiation of the telephone questionnaire.

Personal details will be stored on a password-protected computer held on a secure server at King's College London. This information will be stored separately from any anonymised research data and will be deleted at the end of the study.

The SH:24 website will provide clear signposting to counselling, contraception and abortion services.

Table 4: Derivation of the Kaplan-Meier (K-M) estimate of the survivor function *S(t)*. Data required to construct K-M curves for time from unprotected sexual intercourse (UPSI) to taking emergency contraception (EC) in days for three exposure groups: 1) clinic; 2) pharmacy; 3) SH:24

Exposure	**Interval (days) since UPSI (*t*)**	**Total number of subjects at beginning of interval (n_t)**	**Number of subjects taking EC during interval (d_t)**	**Number censored during interval**	**Number of persons at risk $r_t = d_t/n_t$**	**Probability of taking EC during interval $s_t = 1 - r_t$**	**Cumulative chance of taking EC from event (UPSI)** $s(t) - s(t_{previous}) \times s_t$
Clinic	1						
	2						
	3						
	4						
	5						
	6						
	7						
Pharmacy	1						
	2						
	3						
	4						
	5						
	6						
	7						
SH:24	1						
	2						
	3						
	4						
	5						
	6						
	7						

Telephone Questionnaire Development

Initial drafts have been formulated of the telephone questionnaire for internet-based EC users who consent to follow-up. These will continue to be refined through collaboration with experts and piloting of prototype materials with potential internet-based EC users. An outcome of interest is to identify if SH:24 is meeting unmet need for EC. This has not been formally listed as an outcome as work is still ongoing to establish the most suitable outcome measure. Ideally, the questionnaire would identify the proportion of users who would not have obtained EC without the presence of SH:24, however there is considerable bias in hypothetical responses (376, 377). Questions have been drafted that ask participants to identify perceived barriers to face-to-face services. The questionnaire will be ready for piloting by the 25th August 2015.

Implications

To our knowledge, this is the first study of the effects of an internet-based EC service involving home delivery of the medication. In the absence of a strong body of evidence, it is vital to establish the feasibility and acceptability of this innovation as a starting point for further research

and development. The results of the study will provide the initial evidence about the potential risks and benefits of internet-based EC provision. The design of SH:24 can be responsive to the results of the study by employing findings to adapt and develop the service. The results will also have wider implications for the potential of internet-based EC to broaden access on a larger scale.

The Cox regression will identify intensifying independent variables. It is predicted that the outcome of time from UPSI to EC delivery may be affected by whether or not the UPSI took place on a weekday or weekend because SRH services are either closed or have reduced opening times on Saturdays and Sundays. These results will have implications about the gap in EC service provision that can be filled by internet-based EC.

If internet-based EC is shown to be feasible and acceptable there are various avenues for further research that could be explored. A more rigorous trial could directly compare an internet-based intervention with face-to-face services and allow minimisation of the biases that hamper this study's more naturalistic design. A larger trial could be powered to test for differences in the outcome of pregnancy so that the value of the intervention could be more fully understood, particularly with regard to referral pathways, which, if adhered to, represent successful service delivery in the event that EC users do not attain their requirements at their initial point of access.

Synopsis

Additional details of the study are outlined as follows:

Study Sponsor

Guy's & St. Thomas' Trust (GSTT)

Chief Investigator

Dr Paula Baraitser
Senior Lecturer
King's College London
Weston Education Centre
Cutcombe Road
London
SE5 9RJ

Project timeline and milestones

Study set-up: Months 1-4 (Sept - Dec 2015)

- Obtain ethical approval.
- Test and refine telephone questionnaire.
- Approval for collection of anonymised data for individuals seeking EC will be obtained from management teams of the databases in the designated face-to-face services in Lambeth and Southwark.
- The study website and links to it from the SH:24 site will be arranged and ready to launch.

Data collection: Months 4-8 (Dec - May 2016)

- Week by week data collection will be ongoing at all designated study sites.
- Telephone questionnaire data will be ongoing for consenting SH:24 users.
- Data collection complete by May 2016.

Data analysis: Months 8-10 (May - July 2016)

- Survival analysis completed.
- Analysis of telephone questionnaire completed.

Paper write-up: Months 10-12 (July - Sept 2016)

- Draft paper written and checked/contributed to by academic supervisors and co-authors.
- Paper submitted for publication.

Can remote and active contraceptive delivery and support for users of an internet-based emergency contraception service facilitate their effective use of ongoing contraception?

PROTOCOL Version Two 28.10.15

Project Title

Can remote and active contraceptive delivery and support for users of an internet-based emergency contraception service facilitate their effective use of ongoing contraception?

Research Aims & Objectives

To establish the effectiveness of actively translating users of an internet-based EC service to use of ongoing contraception, by providing a 3-month supply of POP oral contraception in the post accompanied with additional support and information that will be determined by intervention mapping techniques. Objectives are as follows:

- To report the intervention effects on use of POP or other forms of regular, effective contraception at 4 weeks post randomisation.
- To report the intervention effects on use of POP or other forms of regular, effective contraception at 4 months post randomisation.
- To report the intervention effects on the use of any EC services at 4 weeks and 4 months.

Background

Unintended Pregnancy - The Global Context

An unintended pregnancy is that which is reported to have been unwanted or mistimed (51). It is a major public health concern due to its ubiquity (50), its negative impact on birth and maternal health outcomes (2) and its disproportionate effect on women in lower socioeconomic groups (344). It is a financial strain on the resources of national health systems (53, 345). Globally, of the 208 million pregnancies that occurred in 2008, approximately 41% were unintended, which includes 33 million unplanned births, 41 million induced abortions and 11 million miscarriages (50). The average global birth rate among 15 to 19 year olds is 49 per 1000 (346). Mistimed pregnancies are particularly common amongst adolescent and young adult women (51). The consequences of unintended pregnancy for this age group can include the loss of educational opportunities and societal marginalization (50).

Unintended pregnancies are primarily a consequence of non-use of contraception, inconsistent or incorrect contraceptive use or contraceptive failure (378). The global prevalence of contraceptive use amongst women of reproductive age either married or in a union increased from 55% in 1990 to 63% in 2011 (125). Continued efforts to increase access to contraception and reduce remaining unmet need is the primary strategy to tackle rates of unintended pregnancy (7).

Unintended Pregnancy - The National Context

In 2010, there were an estimated 225 600 unintended pregnancies in England directly costing the NHS £193 200 000 (53). Estimates suggest that approximately 16% of all pregnancies in

2011 were unplanned (1). The age-standardised abortion rate was 15.9 per 1000 resident women aged 15-44 in England and Wales in 2013 (348). This is the lowest recorded rate for 16 years. However, unintended pregnancy is still a public health priority (21). The UK adolescent birth rate remains high compared to other developed countries at 9.2 births per 1000 women aged 15-17 (349). There is a 6-fold difference in adolescent conception and birth rates between the poorest and most affluent areas in England (350) and access to contraceptive services is most problematic for people in disadvantaged communities (351).

The majority of women (75%) who are under 50 years of age in Great Britain use at least one method of contraception (352). The National Institute for Health and Care Excellence (NICE) outlines that a commitment to the continued improvement of contraceptive services is necessary to not only further reduce unplanned pregnancies, but also reduce inequalities and improve NHS spending efficiencies (353). Contraceptive services include access to emergency contraception (EC). This has been expanded through patient group directions (PGDs), which allow suitably qualified nurses and pharmacists to dispense free oral EC to young women without prescription (354).

Emergency Contraception (EC)

EC is a vital and effective contraceptive option for women and the only method that can be used after unprotected sexual intercourse (UPSI) or sexual assault or to compensate for the failure of other forms of contraception. There are three EC methods that can be used in the UK: 1.5mg single oral dose levonorgestrel (LNG); 30mg single oral dose of ulipristal acetate (UPA) and the copper-bearing intrauterine device (Cu-IUD) (355).

Despite the body of evidence indicating EC is a valuable and effective approach to pregnancy prevention for the individual, studies report that increasing access to hormonal EC does not reduce overall pregnancy rates (127, 128) or abortion rates (129, 130) or unintended pregnancy rates on a population level (131). Non-use of EC is often related to failure to recognise the risk of pregnancy (132); the neglect of perceived risk (133); inconvenience and fear of side-effects (134). Qualitative studies interviewing young women from urban areas also report stigma; personal difficulties in asking for EC; experiences with healthcare professionals and misperceptions about the method as further barriers to EC (135, 136). It may be that the current configuration of EC services are not meeting the needs of all women (137) and that interventions that have sought to increase access have not targeted those most at risk (138, 139).

Facilitating Uptake of Effective Contraception After EC Use

According to guidelines from The Faculty of Sexual & Reproductive Healthcare (FSRH), healthcare professionals should have a discussion about suitable contraceptive methods with all women attending services for EC (379). 95% of women will not become pregnant after using EC so remain at risk of pregnancy unless they resume or begin another method of effective

contraception (358, 380, 381). A meta-analysis of over 4500 women who had sexual intercourse in the period after use of EC but before the return of menses reported a relative risk of pregnancy of 2.61 (CI 2.0 - 3.4) when compared to women who abstained during this time (382).

There is very limited research on the best way to facilitate uptake of effective contraception after EC use. Even within specialist SRH services, where expertise and a range of contraceptive methods are readily available, uptake can be surprisingly low (383, 384).

Recent research has focused on facilitating effective contraception for women obtaining their EC from pharmacies because of the concern that these access points are likely to be less well-equipped at dealing with additional contraceptive needs when compared to SRH services. Additionally, access to EC via pharmacies is very popular in the UK due to convenient opening times, no appointments and rapid access (385, 386). The lack of readily available expertise and methods can be a barrier to those women accessing pharmacy EC who would prefer to use more effective, regular contraception to avoid pregnancy (385, 387, 388). A recent feasibility study in Scotland indicated that both a fast track referral to a specialist contraceptive clinic or a month supply of progestogen-only pills (POP) resulted in a significant improvement in the number of women using effective contraception at 4-6 weeks after taking EC compared to standard care (389). Of those women in the POP intervention arm who were not lost to follow-up, 90% used the POP provided and 56% were using effective contraception at 6-8 weeks post EC, compared to 16% in the control arm who received standard care alone.

Internet-based Contraception Services

The capacity for existing services to continue to cater for growing demand for contraception is not assured (11). The nature of this demand is also shifting, with technology-mediated models of service delivery pioneered in the private industry, becoming increasingly widespread in healthcare (361). Evidence regarding the public health benefits of online testing for sexually transmitted infections (STIs) is growing (362). In contrast, online services for contraception in the UK remain restricted to the private sector (363, 364) and, where freely available, are limited to information-only or signposting facilities, such as the contraceptive components of the National Health Service's NHS Choices site (365) or My Contraception Tool (36).

Innovation in service delivery via an internet-based system has the potential to overcome many of the barriers that have hindered EC from having a population-level impact by offering a new route of supply to free EC. There is some limited evidence to suggest acceptability of and demand for internet-based sexual and reproductive health services, often citing privacy of access and convenience as advantages of this mode of delivery (164, 342, 366, 367).

Sexual Health 24 (SH:24) aims to expand access to clinical services by providing contraception and diagnosis and management of STIs via an internet-based service linked to telephone and specialist clinic support. The internet-based STI testing and diagnostics component was

launched in March 2015 and in December 2015 it will launch access to EC and POP via the same website. SH:24 services are restricted to those aged 16 years and above and residents of the boroughs of Lambeth and Southwark.

Rationale

SH:24 will support their users of EC in seeking protection from the future risk of unwanted pregnancy. However, the most effective way to achieve this is currently unknown.

Pharmacy access to EC provides a useful model for innovation in service delivery (127, 385) - informing our expectations about the potential risks and benefits of internet-based access. We predict that, as has been demonstrated in users of pharmacy-EC, users of the internet-based service will be attracted to the convenience, speed and anonymity of internet access and home delivery. Pharmacy providers are now progressing towards offering more active bridging services to ongoing contraception so that their EC users do not lose out on the immediate availability of contraceptive options that users of clinical services can benefit from (389, 390). An internet-based service can use similar techniques to progress beyond signposting.

This RCT will establish the effectiveness of actively translating users of an internet-based EC service to use of regular, effective contraception, by providing a 3-month supply of POP in the post. The first stage of the process will establish what additional support will be required to optimise this intervention through use of an adapted intervention mapping protocol. The second stage will evaluate the success of the intervention when compared to internet-based EC with standard care alone. This will reveal if remote and active contraceptive delivery and support for users of an internet-based EC service will facilitate their effective use of short-term ongoing contraception. It will also expand our understanding of the potential value of internet-based services to reduce unmet contraceptive need on a longer-term basis.

Research Context

Lambeth and Southwark are adjacent inner London boroughs which are ethnically diverse and densely populated with high levels of deprivation (368, 369). However, there are also pockets of affluence in the boroughs and the high proportion of young people of working age allow for a very economically active population.

The boroughs have rates of abortion, repeat abortion and unintended pregnancy that exceed national averages (368, 369). An analysis of abortions performed by local providers between 2008 and 2013 shows that rates are much higher in those who identify as Black/African/Caribbean/Black British or Other Ethnic Group (162).

The residents of these boroughs have access to a range of services providing free contraception. There are open access, walk-in, integrated SRH services such as Camberwell Sexual Health Centre, as well as community clinics and Brook services. Many people also attend GPs for their contraceptive needs (370). It can be problematic for some people to access these services because of inconvenient opening times, long waiting times and high numbers of people being turned away (9, 11, 371). The comparative speed and convenience of access to pharmacies explains their popularity as access points for EC, with 11784 free EC consultations reported in the boroughs in 2013-14 (372) relative to just 3853 in GPs (370).

The Local Authorities (LAs) in these boroughs are committed to reducing rates of unintended pregnancy and repeat terminations within a context of proposed public health spending cuts in the face of rising clinical activity (162, 373). Part of their strategy is to shift non-complex activity to SH:24 in order to allow SRH and other services to dedicate more time to complex cases.

Methods: Design Strategy & Framework

The methodological strategy necessitates a two-stage process in order to firstly, develop the components of the intervention that are provided in conjunction with the remote and active delivery of POP and secondly, to strategize the execution of the RCT.

STAGE ONE: Planning the intervention

1. Use the ToC to produce a needs assessment for the specific issue of facilitating the use of contraception for service-users of internet-based EC in order to solidify the research context, aims and objectives.
2. Create a matrix of change objectives to focus the intervention by defining and grouping the objectives and exploring the determinants of change.
3. Identify the theoretical methods that can influence change in determinants and identify the conditions in which a given method is likely to be effective. This can be used to choose the most appropriate theoretical approaches for the intervention.
4. Consult with a focus group of potential study participants to develop the intervention materials. The focus group should be representative of typical SH:24 users so recruitment will be from the participants that consented to follow-up in Study Two.
5. After development of prototype materials, these will be tested on the focus group and reviewed accordingly.
6. The results of the focus groups will help to:
    a. Develop the intervention scope and sequence.
    b. Describe each population group and program interface including the mode of communication between researchers and participants.
    c. Determine the intervention budget.

STAGE TWO: Implementation of the intervention

A single blind randomized controlled trial (RCT) to report the effectiveness of remote and active contraception delivery and support to translate users of an internet-based EC service to uptake regular, effective contraception. Internet-based EC service users who meet inclusion criteria and consent to participate will be randomised using a 1:1 allocation ratio to either the intervention group or control group (Figure 4). The intervention will include a 3-month supply of (POP) in the post accompanied with additional support that will be determined in Stage One. Women in the intervention arm will also receive a supply of condoms. All participants will be followed up at 4 weeks and 4 months post use of the internet-based EC service to compare uptake of POP or other forms of effective contraception.

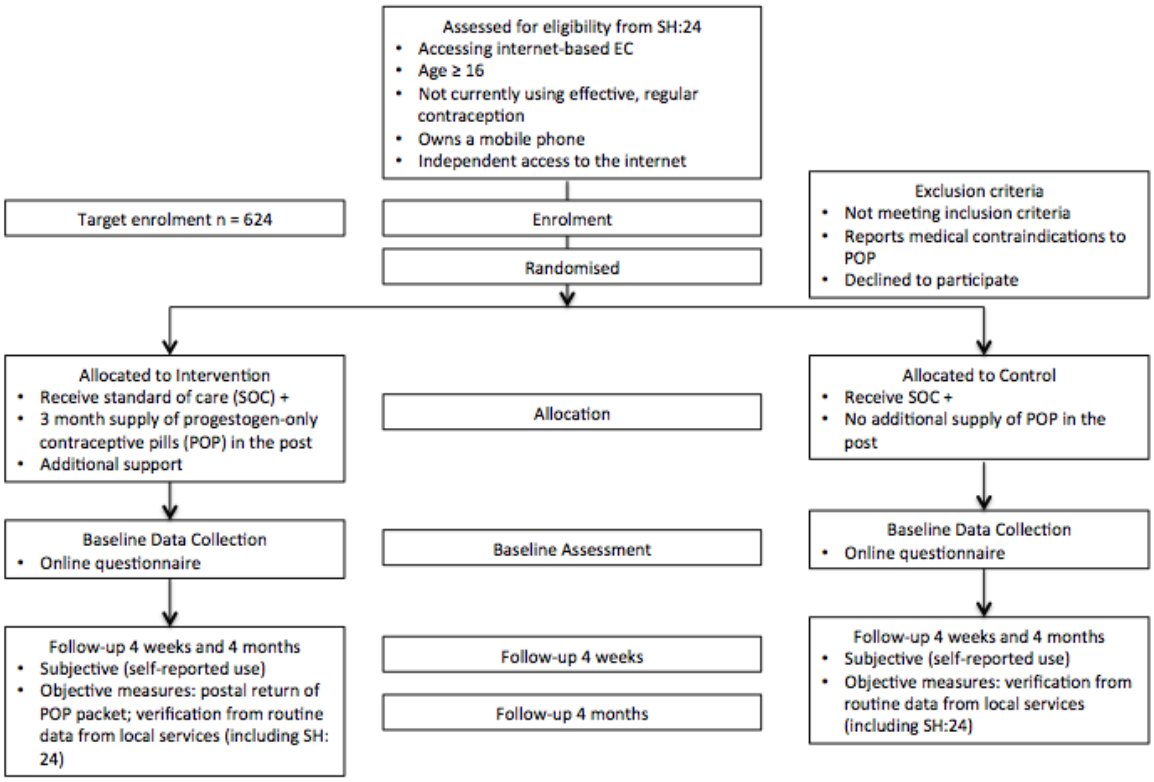


Figure 1 Study Flowchart

Sample Size Calculation

A minimum recruitment of 624 clients is estimated to obtain at least 80% power to detect an increase of at least 10% in the adoption of a regular contraceptive method in the intervention group compared to the control group, based on a one-sided test with a 5% significance level. This sample size estimation assumed that regular contraceptive use in the control group would be 16%, as estimated based on a pharmacy-based pilot study (389). Based on initial results from an RCT on STI testing and diagnosis in a similar study population (Wilson E [Study Coordinator and First Author] 2015, oral communication, 18th May), the sample size was adjusted to account for loss to follow-up (20%).

It is estimated that recruitment from SH:24 will take 6 - 12 months at a rate of approximately 50 - 100 per month, based on service use in May and June of this year (374).

Data Collection

Data will be collected via remote interaction with subjects. The channels of interaction will be determined from the results of Stage One.

Inclusion Criteria

- Accessing EC from SH:24 during the recruitment period (and thus meeting the eligibility criteria of this service).
- Aged 16 years or above.
- Independent access to a mobile telephone.

- Independent access to the internet - via a personal computer; laptop; smartphone; or tablet.

Exclusion Criteria

- Currently using and intending to continue using an effective oral contraceptive method or the contraceptive patch.
- Currently using any form of Long-Acting Reversible Contraception (LARC).
- Any medical contraindications to POP use as specified in UK Medical Eligibility Criteria for Contraceptive Use for POP use (87).

Recruitment and Consent

All women accessing EC from SH:24 during the recruitment period will be invited to participate in the trial by the appearance of brief synopsis of the trial and a link to the study website. Here the invitees will be presented with further information and a list of eligibility criteria.

Should they choose to participate they will be asked to provide informed consent via the study website. They will then be asked to provide baseline data. A computerised randomisation system will allocate them to either the control or intervention arm.

Intervention

A 3-month supply of POP will be provided in the post. Study participants will receive additional support and information that will be determined by the results from Stage One. In addition to the POP, participants will receive a supply of condoms and will be advised to use these during sexual intercourse for the prevention of STIs. It is also recommended that condoms are used during sexual intercourse for 9 days after taking UPA in accordance with FSRH guidelines (379). Participants will be followed up at 4 weeks and 4 months with a telephone questionnaire to acquire self-reported data on their regular, effective contraceptive use. At 4 months they will be provided with a prepaid envelope to return the POP packet that was sent to determine the uptake of the supply.

Control

Participants in the control arm will receive standard care as provided by SH:24. Participants will be followed up at 4 weeks and 4 months with an internet-based questionnaire to acquire self-reported data on their regular, effective contraceptive use.

Table 1 Outcome Measures and Methods of Analysis

Outcome	Outcome measure	Method of analysis
1. Primary		
Use of an effective method of contraception at 4 months	Objective (binary) Self-report (binary)	1. Chi-squared test 2. Mantel–Haenszel test for linear association
2. Secondary		
Uptake of the POP delivered at 4 weeks	Objective (binary) Self-report (binary)	Chi-squared test
Use of EC at 4 weeks and 4 months	Self-report (binary) Objective (binary)	1. Chi-squared test 2. McNemar's Test
Change in contraceptive use at 4 weeks and 4 months	Self-report (binary) Objective (binary)	McNemar's Test
Use of an effective method of contraception at 4 weeks	Objective (binary) Self-report (binary)	Chi-squared test
Use of SH:24 to order another supply of POP at 4 months	Objective (binary)	Chi-squared test
Use of services other that SH:24 to obtain contraception at 4 months	Objective (binary) Self-report (binary)	Chi-squared test
Pregnancy	Self-report (binary) (0, 1 or more)	Chi-squared test
3. Per protocol analysis	All outcomes	Chi-squared/ t-test/logistic and linear regression
4. Sub-group analysis	All outcomes	Logistic/linear regression
Age		
Ethnicity Socioeconomic Status		

Data Analysis

Associations between factors at baseline will be investigated using Chi-squared tests and the Mantel–Haenszel test for linear association. McNemar's test will be used to examine changes in contraceptive use at 4 weeks and 4 months. Test for significant differences in proportions between the intervention and control arms for all outcome measures will be tested for at a 5% significance level.

Analysis of the primary outcome will be based on the 'intention to treat' principle. Therefore, users will be analysed according to the arm to which they were randomised and participants lost to follow-up will be considered non-users of effective, regular contraception.

Per-protocol analysis will be undertaken to assess the effects of the intervention on the participants who fully experienced it.

Outcomes

A conceptual visualisation of plausible outcomes (Figure. 5) has contributed to the development of the outcome measures.

Outcome Measures

Baseline characteristics of study participants will be compared with those of the general population of the internet-based contraceptive service. The following will be assessed:

- Recruitment rates.
- Numbers assessed for eligibility compared with numbers actually enrolled.
- Completeness of follow-up.

Primary Outcomes

1. % participants using POP or other form of regular and effective contraception at 4 months post randomisation.

Regular and effective contraception is defined as those methods that are associated with 10% 12 month pregnancy rates including LARC and oral contraceptive pills (391).

Secondary Outcomes

1. % participants using POP or other form of regular and effective contraception at 4 weeks post randomisation.
2. % participants who used an EC service one or more times due to UPSI at 4 weeks and 4 months post randomisation.
3. % participants in intervention arm who use POP provided in the post at 4 weeks and 4 months.
4. % participants in the intervention arm who return to the internet-based service for an ongoing supply of POP.
5. % participants who use alternative services to obtain contraception at 4 weeks and 4 months.
6. % change in contraceptive uptake at 4 weeks and 4 months.
7. % pregnant at 4 months.

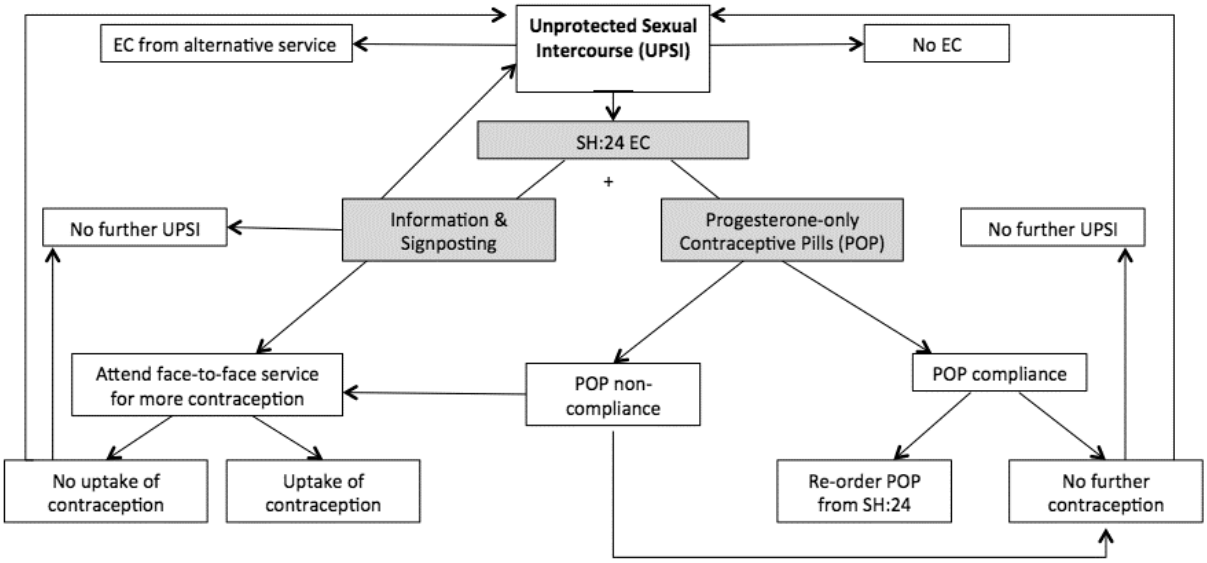


Figure 2 Conceptual Algorithm of Plausible Intervention Outcomes

Limitations

The objective measure of asking participants to return the POP packets at 4 months to determine uptake may contain some bias. Those who complete the regimen may be more inclined to return the packet than those that do not complete it or do not take it at all. Self-reported measures will be relied upon in the event that the proportion returning the POP packet is low, which will be subject to social desirability bias.

There are several components that are operating within the intervention arm. It will be challenging to identify whether the outcomes will be a result of one particular component or all of them combined.

The follow-up period is relatively short. Therefore, we will only draw conclusions about the impact of the intervention on contraceptive uptake on a short-term basis. This may elucidate the potential value of further studies around long-term use of internet-based contraceptive services. Pregnancy is listed as a secondary outcome, but it is likely this occurrence within the study population will be too rare to render significant analysis.

Ethical issues: consent, access and participants' protection

All participants will be provided with online information about the trial via the study website. The site will also provide details of the study coordinator so participants have a person to contact should they require further information.

Implications

This trial will provide rigorous evaluation of a novel intervention to support internet-based EC and will contribute towards the evidence base on interventions to translate EC users to ongoing, effective contraception and the capacity of internet-based interventions to prevent unintended pregnancy.

This is likely to be the first RCT of internet-based delivery of contraception and will pave the way for further research and development. The results of this study will give a preliminary indication of the short-term effect of the intervention, elucidating the potential value of further investigation. Longer-term follow-up of the participants will establish the effectiveness of remote and active facilitation of ongoing contraception uptake for internet-based EC users at 6 and 12 months post randomisation. At these time points it will also be possible to obtain data for a secondary specific outcome on the rate of pregnancy in each arm. This length of follow-up is beyond the scope of this PhD. I intend to apply for post-PhD funding for extension of the follow-up period.

This follow-up will also include qualitative interviews of a purposive sample of intervention recipients in order to explore the experiences of both users and non-users of contraception. This will identify the active components of the intervention to contribute to service development of internet-based contraceptive services.

Synopsis

Additional details of the study are outlined as follows:

Study Sponsor

Guy's & St. Thomas' Trust (GSTT)

Chief Investigator

Dr Paula Baraitser
Senior Lecturer
King's College London
Weston Education Centre
Cutcombe Road
London
SE5 9RJ

Project timeline and milestones

Study set-up: Months 1-8 (Nov 2015 - Jun 2016)

- Obtain ethical approval.
- Create needs assessment and matrix of change as specified by the intervention planning techniques.
- Determine relevant theoretical methods.
- Determine each population group and program interface including the mode of communication between researchers and participants.
- Develop intervention materials, scope, sequence and budget.
- The study website and links to it from the SH:24 site will be arranged and ready to launch.

Data collection: Months 9-21 (Jul 2016 - Jul 2017)

- Recruitment to the trial will occur during the first 6 months of the data collection period.
- Baseline data collected.
- Postage of intervention materials.
- Collection of follow-up data at 4 weeks post randomisation.
- Collection of follow-up data at 4 months post randomisation.

Data analysis: Months 21-25 (Jul - Nov 2017)

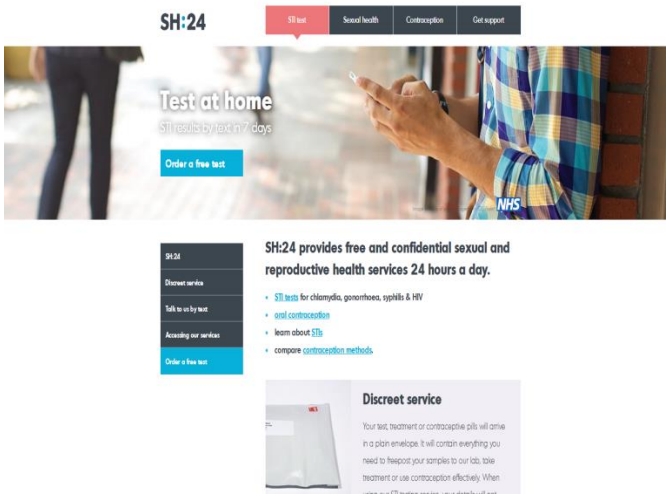
- Trial site closed and data cleaned.
- Data analysis: tests for associations of factors at baseline, analysis of changes in outcome measures at 4 weeks and 4 months and tests for differences in proportions between arms (intention to treat and per protocol).

Paper write-up: Months 25-27 (Dec 2017 - Feb 2018)

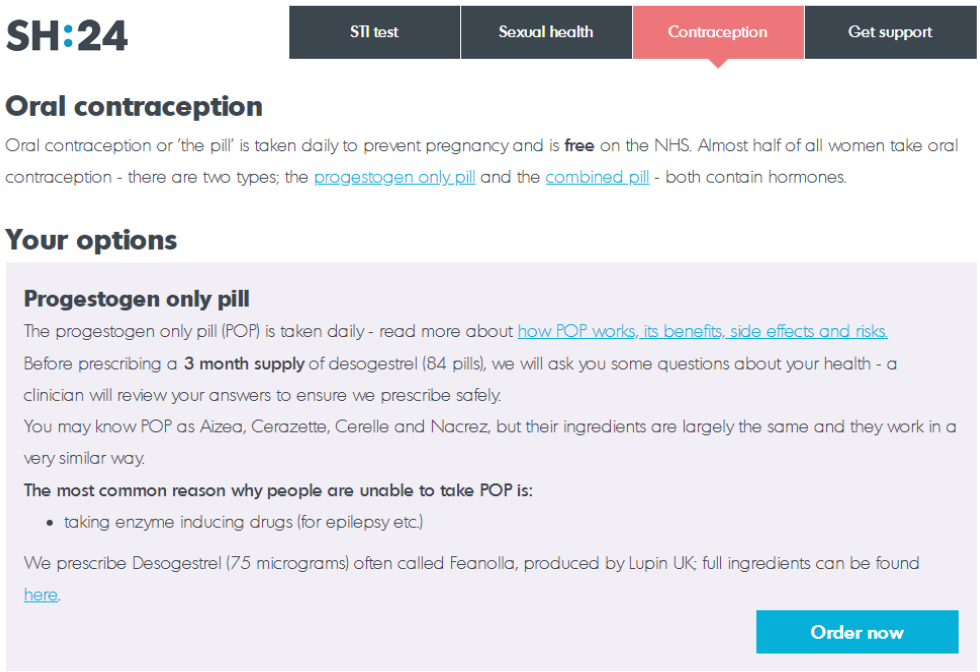
- Draft paper written and checked/contributed to by academic supervisors and co-authors.
- Paper submitted for publication.

Appendix C. Screenshots of the online contraception intervention, SH:24

1. Landing page



2. Oral contraception information page



Combined pill

The combined pill (COC) is taken daily - read more about how the combined pill works, its benefits, side effects and risks.
Before prescribing a **3 month supply** of ethinyoestradiol, levonorgestrel (63 pills), we will ask you a number of questions including if you smoke, your blood pressure, your weight and height - a clinician will review your answers to ensure we prescribe safely.
You may know the combined pill as Microgynon, Rigevidon, Yasmin and Loestrin 30, but their ingredients are largely the same and they work in a very similar way.

The three most common reasons why people are unable to take COC are:

- suffering from migraines with aura (changes to your vision and/or pins and needles or numbness, before, during or after the headache begins)
- having high blood pressure
- a family history of blood clots.

We prescribe Levonorgestrel / Ethinylestradiol (150 micrograms) often called Levest, produced by Morningside Pharmaceuticals; full ingredients can be found here.

Order now

Other types of contraception

There are many types of contraception, so you can choose the right method for your lifestyle. Don't be put off if the first type you use isn't quite right - you can try another.

Other types

Ordering from SH:24

We will ask you a number of health questions to assess your suitability for oral contraception - these are exactly the same questions that you would be asked by your GP or at a sexual health clinic. If you have any queries or need help when ordering, a clinician will be available to advise you.

Once the SH:24 clinician has approved your prescription, we will post your contraception out the same day (if you order before 2pm), or the next working day (if you order after 2pm). SH:24 provide the same oral contraception as NHS clinics and pharmacies. We will send it in **discreet packaging** by 1st class Royal Mail. You will not have to be in or sign for the package - it will fit through your letter box.

3. List of frequently asked questions

Questions?

Tell me more about the combined pill SH:24 prescribes.	1
How quickly will oral contraception start working?	1
What does the packaging look like?	1
I am thinking of changing methods of contraception, can SH:24 help?	0
I am currently taking oral contraception • how do I know which type of pill I'm taking?	0
Should I take oral contraception or use a long lasting contraceptive like a coil or implant?	0
I don't know my blood pressure • what do I do?	0
How many months supply of oral contraception will SH:24 prescribe?	0
Can I request a record of my previous oral contraception orders from SH:24?	0
Are there side effects of taking oral contraception?	0
Which type of oral contraception should I order?	0
Can I track my order?	0
What do I do if it doesn't arrive?	0
Who will sign my prescription?	0
I've recently had unprotected sex • what should I do?	0
I am about to have major surgery, can I take the pill?	0
□Tell me more about the progestogen only pill SH:24 prescribes.	0
Do I need to be in to receive my oral contraception, and will it fit through my letter box?	0

How else can we help?

- Learn more about other contraceptive methods
- Speak to a SH:24 clinician about your options: text 07860 041 233 or webchat
- Find a local clinic or pharmacy

4. List of contraceptive methods for which information is provided

- Contraception
- Condom (male)
- Combined pill
- Progestogen only pill
- Implant
- Hormonal coil
- Non-hormonal coil
- Injection
- Patch
- Ring
- Diaphragm
- Condom (female)
- Female sterilisation
- Vasectomy
- Emergency contraception
- Clinics & pharmacies
- Order oral contraception

Contraception

Contraception helps you control if and when you become pregnant.

There are many types of contraception, so you can choose the right method for your lifestyle. Don't be put off if the first type you use isn't quite right – you can try another.

It's important that you are comfortable using your chosen method, and that you know how effective it is.

Only condoms protect you from sexually transmitted infections (STIs) as well as pregnancy.

Contraception is free through the NHS. Some contraception can be bought over the counter, but most are available on prescription through your local sexual health clinic or GP.

You can order oral contraception now from SH:24 for free.

Worried?

- If you have **recently had unprotected sex**, look at your emergency contraception options
- If you have **missed a pill**, read here for how to stay protected
- If you have any questions, you can talk to one of our clinicians via webchat

Your options

All	Emergency	Hormone free
Long lasting	STI protection	Taken daily

Condom (male)

A sheath or covering that is worn over the penis during sex. Designed to stop a man's semen from coming into contact with his sexual partner.

Combined pill

A small round tablet that releases artificial versions of the oestrogen and progesterone hormones. It has to be taken daily.

Progestogen only pill

Also known as 'POP', is a small round tablet that releases a progestogen hormone. It has to be taken daily.

Implant

A small, flexible plastic tube that sits under the skin of your upper arm and releases the progestogen hormone.

Hormonal coil

Also known as the IUS (intrauterine system), is a small T-shaped plastic device that sits in your womb and releases the progestogen hormone.

Non-hormonal coil

Also known as the IUD or 'copper coil', is a small T-shaped device that sits in your womb. It is a very effective emergency contraceptive up to five days after unprotected sex.

Injection

The injection contains the hormone progestogen and offers medium term prevention of pregnancy.

Patch

A small, sticky patch that sticks to your skin and releases hormones into your body.

Ring

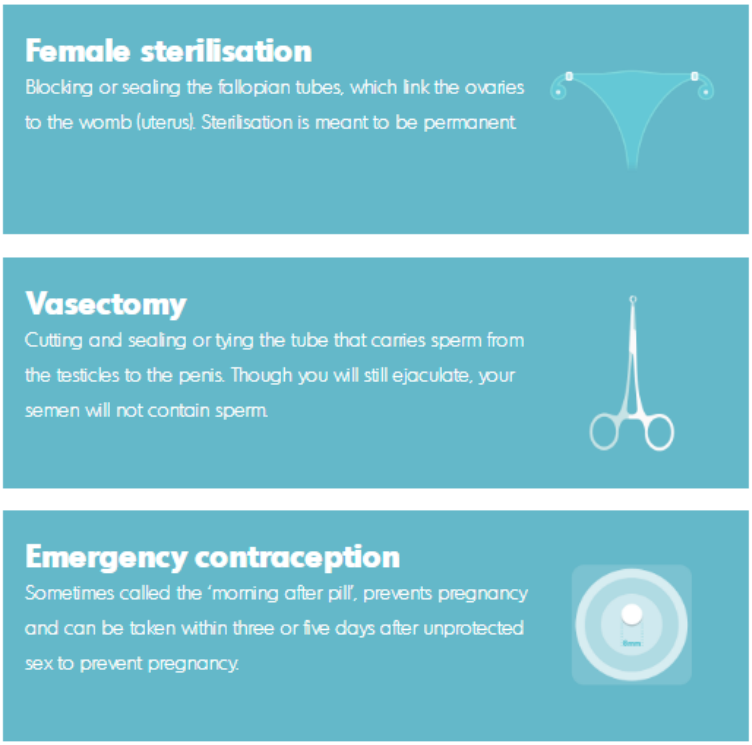
A small, soft plastic ring that you place inside your vagina. It releases the hormones oestrogen and progestogen.

Diaphragm

Domes made of soft silicone. You insert them into your vagina before sex to cover the cervix, so that sperm cannot get into the womb.

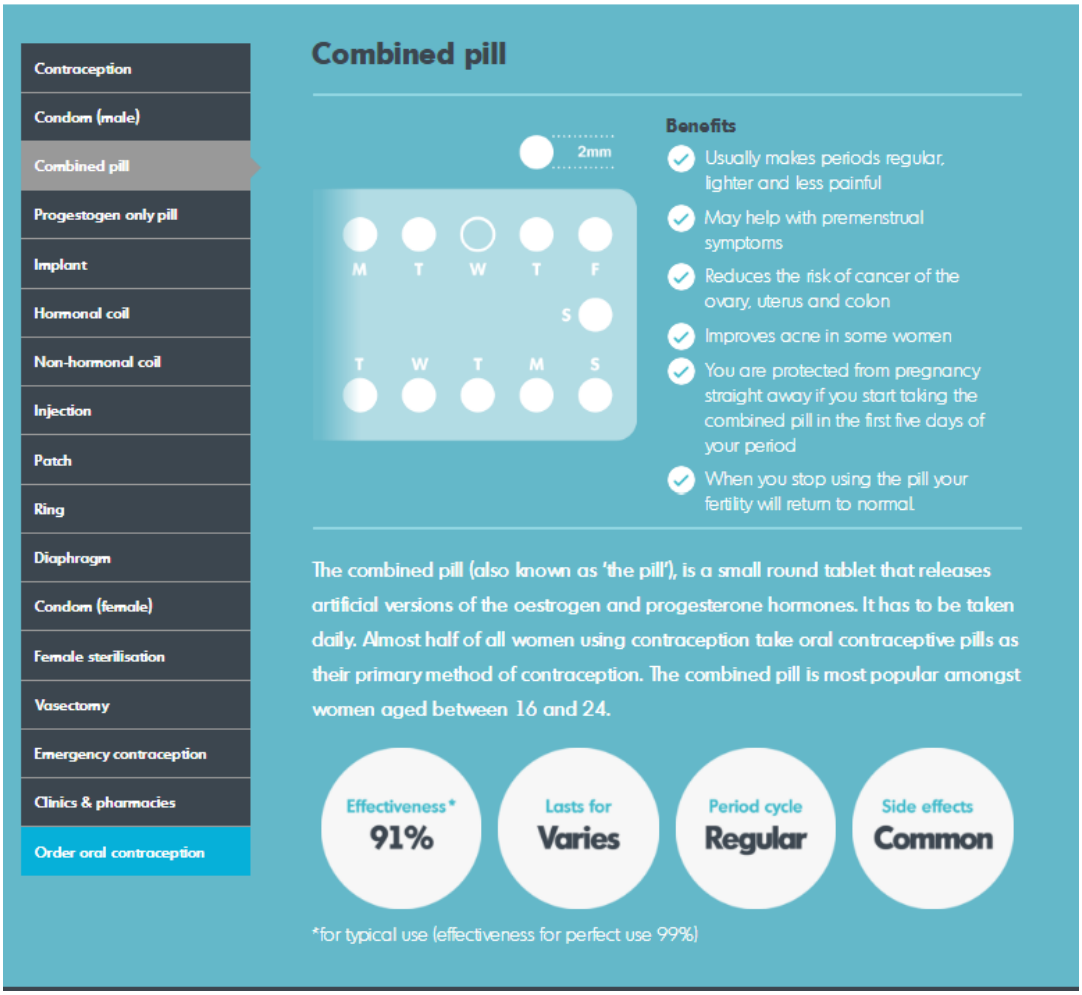
Condom (female)

Often called 'Femidom', are made from very thin soft plastic, and are worn inside the vagina to prevent semen getting to the womb.



(Further information provided about each method – only screenshots of OCP information provided below)

5. Combined pill further information



How it works

How to use it

There are different types of combined pill, which use different brand names. The most common are 21 day pills, where you take one pill every day for 21 days, then stop for 7 days (to follow your 28 day menstrual cycle). Another option is to take 'every day' pills – you take one pill every day with no break, but 7 of these are 'dummy' pills which do not contain any hormone.

Watch a video of one of our clinicians explaining how to take the combined pill

Why it works

The hormones in the combined pill prevent pregnancy by:

- Thickening the mucus in the neck of the womb, so it is harder for sperm to penetrate the womb and reach an egg
- Thinning the lining of the womb, so there is less chance of a fertilised egg implanting into the womb
- In some women, the combined pill also stops the ovaries from releasing an egg (ovulation), but most women will continue to ovulate.

Things to consider

The combined pill does not protect you from STIs. You should use a condom as well if you think you are at risk of an STI.

You need to remember to take your pill every day. If you find that you often forget to take your pill, there are long lasting contraception options available.

Timescale

There are three main types of combined pill. You should follow the instructions in your packet as each type will be different. If you have any questions about how to take your pill, ask your GP, practice nurse or pharmacist. It's important to take the pills as instructed, because missing pills or taking them at the same time as certain medicines may make them less effective at preventing pregnancy.

Monophasic (21-day)

This is the most common type. Each pill has the same amount of hormone in it. One pill is taken each day for 21 days and then no pills for the next 7 days.

Common brands include: Microgynon, Brevinor and Cilest.

Phasic (21-day)

Phasic pills contain two or three sections of different coloured pills in a pack. Each section contains a different amount of hormones. One pill is taken each day for 21 days and then no pills for the next 7 days. Phasic pills need to be taken in the right order.

Common brands include: Binovum and Logynon.

Every day

There are 21 active pills and 7 inactive (dummy) pills. The two types of pill look different. One pill is taken each day for 28 days with no break between packets of pills. Every day pills need to be taken in the right order.

Common brands include: Microgynon ED and Logynon ED.

The pill can become less effective at preventing pregnancy if:

- You have vomiting and/or diarrhoea, as the pill may not absorbed into your bloodstream. Read more in our Questions section.
- You are taking some medicines. Ask a clinician or pharmacist and read the information that comes with your medicine. Always tell your doctor that you are taking the combined pill if you are prescribed any medicines.

What if?

You miss a pill:

The chance of getting pregnant depends on when the pills are missed and how many pills are missed. Read more in our Questions section.

If you are not sure what to do, continue to take your pill and use another method of contraception, such as condoms, and seek advice from your local sexual health clinic, pharmacy or GP.

Suitability

Most women can take the combined pill, but your clinician or GP will ask about your family and medical history to determine whether or not it is the best method for you.

The combined pill is not always suitable for women who:

- Are pregnant
- Smoke (or stopped smoking less than a year ago) and are 35 or older
- Are very overweight

It may also be unsuitable if you have or have had certain health conditions.

Side effects & risks

Although serious side effects are not common, there are some risks associated with the combined pill.

	Common	Rare
Short term:	Can cause temporary side effects such as headaches, nausea, breast tenderness and mood swings – these often improve over time but can be persistent. Some bleeding and spotting in the first few months.	
Long term:	Some loss of libido. Changes to skin.	Can increase your blood pressure. Small increased risk of some serious health conditions, such as thrombosis (blood clots) and breast cancer or cervical cancer. These risks reduce with time after stopping the pill. Can cause hair loss and Chloasma (dark patches over the face).

You should discuss any concerns with your clinician or GP.

Questions?

How quickly does the combined pill start protecting me against pregnancy?	1
What happens if I miss a pill?	1
What if I vomit or have diarrhoea whilst taking the pill?	1
Will the pill affect my future fertility?	1
Are there any possible longer term side effects of taking the pill?	0
Why do the pill packets look different?	0
Why does the doctor only give me a couple of months' supply of the pill?	0
How will the pill affect my period?	0
Who is the combined pill not suitable for?	0
Why does the combined pill affect my periods?	0
Can medication affect my pill?	0
Does the combined pill cause cancer?	0
Does the pill cause weight gain?	0
Can I take my next pack of pills straight away to miss a period?	0
How does the combined pill affect the menopause?	0
Can I take the combined pill after having a baby?	0
Can I take the combined pill after a miscarriage or abortion?	0
Can the combined pill affect my mood or make me feel depressed?	0
I don't like the thought of taking medication for a long time. Will there be any long term effects on my health if I take the combined pill for several years?	0

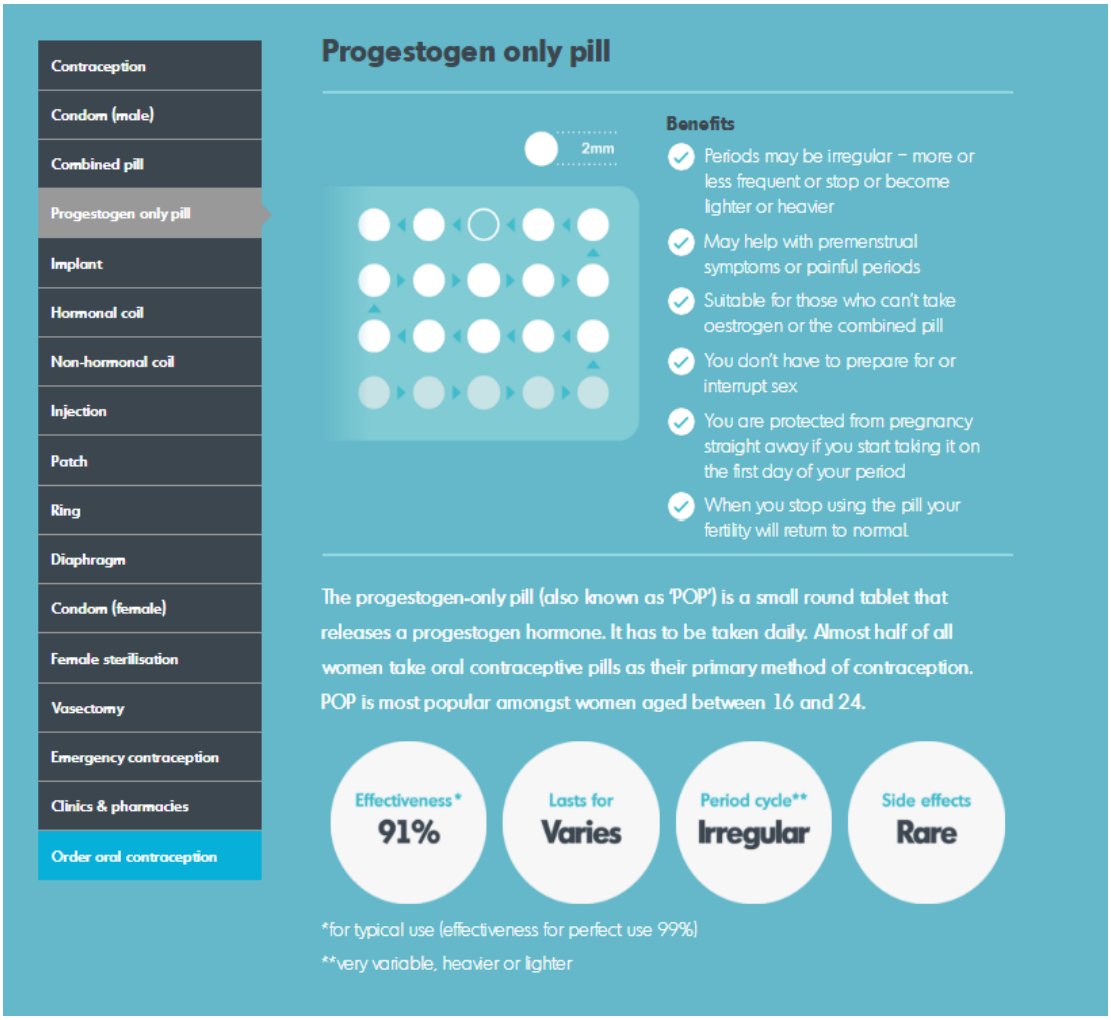
Where can I get it?

The combined pill is available free on the NHS. You should visit your sexual health clinic or GP to discuss your suitability.

You can also order the combined pill now from SH:24 for free.

Order now

6. Progesterone-only pill further information



How it works

How to use it

You will need to take one pill every day. There are 28 pills per pack, and you do not take a break between packs. There are two different types of POP: '3 hour' pills must be taken within the same 3 hour period every day. '12 hour' pills must be taken within the same 12 hour period.

Choose a convenient time in the day to take your first pill, and continue to take it close to that time every day.

Watch a video of one of our clinicians explaining how to take POP.

Why it works

The hormone in POP prevents pregnancy by:

- Thickening the mucus in the neck of the womb, so it is harder for sperm to penetrate the womb and reach an egg
- In some women, POP prevents the ovaries from releasing an egg each month (ovulation)
- Thinning the lining of the womb, so there is less chance of a fertilised egg implanting into the womb.

Things to consider

POP does not protect you from STIs. You should use a condom as well if you think you are at risk of an STI.

You need to remember to take your pill every day. If you find that you often miss a pill, there are long lasting contraception options available.

What if?

You miss a pill:

- The chance of getting pregnant depends on when the pills are missed and how many pills are missed. Read more in our Questions section
- If you are not sure what to do, continue to take your pill and use another method of contraception, such as condoms, and seek advice from your sexual health clinic or GP as soon as possible.

The pill can become less effective at preventing pregnancy if:

- You have vomiting and/or diarrhoea, as the pill may not be absorbed into your bloodstream. Read more in our Questions section
- You are taking some medicines. Ask your clinician or pharmacist and read the information that comes with your medicine. Always tell your doctor that you are taking the progestogen only pill if you are prescribed any medicines
- Follow the instructions in your packet. If you have any questions about taking the pill, ask your clinician or pharmacist. It's important to take the pills as instructed to ensure they are effective.

Suitability

Most women can take POP, but your clinician will ask about your family and medical history to determine whether or not it is the best method for you.

POP is useful for women who cannot take oestrogen, or those who smoke and are 35 or over.

POP is not always suitable for women who:

- Think they may be pregnant
- Are taking certain medicines
- Have or have had certain health conditions.

Side effects & risks

Although serious side effects are not common, there are some risks associated with POP.

	Common	Rare
Short term:	Spotty skin, breast tenderness, nausea / vomiting, stomach upset, weight change and headaches, change to sex drive or mood. These should go after a few months.	
Long term:	Periods may be irregular, lighter, heavier or more frequent or may stop altogether.	Some women may develop small fluid-filled cysts on their ovaries. These are not dangerous and do not usually need to be removed.

You should discuss any concerns with your clinician.

Questions?

I've heard that some women get cysts from POP? Are these serious? 0

How quickly does POP start protecting me against pregnancy? 0

What is the difference between the various brands of POP? 0

What if I miss a pill? 0

What if I vomit or have diarrhoea whilst taking the progestogen only pill? 0

I've had a serious health condition. Can I take POP? 0

Can I take POP if I'm approaching menopause? 0

I don't like the thought of taking medication for a long time. Will there be any long term effects on my health if I take the POP for several years? 0

Can taking POP increase the risk of developing cancer? 0

Why does POP affect my periods? 0

Why does the doctor only give me a couple of months' supply of the pill? 0

Why do the pill packets look different? 0

Is the POP pill less likely to give me mood swings and other side effects than the Combined pill? 0

I am on the 3 hour window pill, can I change to the 12 hour window one? 0

Does the progestogen only pill cause weight gain? 0

Can medicines affect how the pill works? 0

Will the POP affect my future fertility? 0

Can I use POP after having a baby? 0

Can I use POP whilst breastfeeding? 0

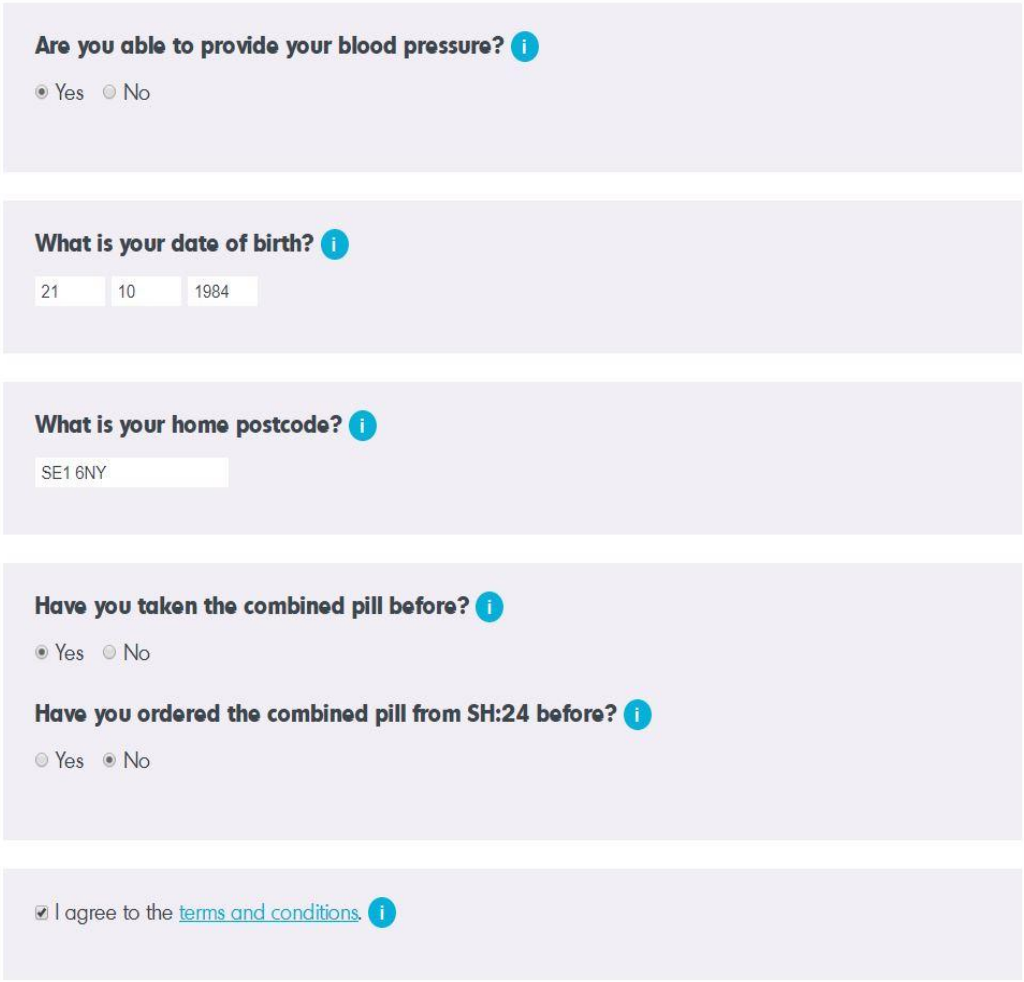
Where can I get it?

The POP is available free on the NHS. You should visit your sexual health clinic or GP to discuss your suitability.

You can also order the progestogen only pill now from SH:24 for free.

Order now

7. Questions asked to service-users ordering COC



What is your blood pressure?

Your health may be at risk if you provide inaccurate answers - if you are unsure, please talk to one of our clinicians by text (07860 041 233) .

Top number (Systolic) 100

Bottom number (Diastolic) 70

A reading of 140/90 or above is known as high blood pressure.

Women aged 30-34 who have high blood pressure and take the combined pill:

A clinician will call you to discuss your options if your blood pressure is high.

What is your height?

- (•) in cm 165

or

- ( ) in feet and inches

What is your weight?

- ( ) in kg

or

- (•) in stone and pounds 9 lbs

Have you had a baby in the last 2 months?

- ( ) Yes (•) No

Are you breastfeeding?

- ( ) Yes (•) No

Have you had a 'normal' period in the last 4 weeks?

By 'normal' we mean a period which you experience on a regular basis.

◉ Yes ○ No ○ I don't normally have a period

Have you experienced any unusual vaginal bleeding in the last 2 years?

○ Yes ◉ No

Have you had unprotected sex (without using contraception such as an IUD (coil), pills or condoms) since your last period?

○ Yes ◉ No

Are you allergic to oestrogen or progestogen?

○ Yes ◉ No

Are you taking prescription medications or the herbal medicine St John's Wort?

○ Yes ◉ No

Has anyone in your close family (mother/father/brother/sister) had a blood clot, stroke or heart attack under the age of 50?

○ Yes ◉ No

Have you ever had blood clots, a stroke or mini-stroke, heart disease (inc. heart attack), irregular heartbeat, high cholesterol or problems with your heart valves?

○ Yes ◉ No

Do you have two or more relatives who have had breast cancer?

○ Yes ◉ No

Have you ever had breast cancer?

Or are you a carrier of any genes that predispose to breast cancer, specifically BRCA1?

○ Yes ◉ No

Have you ever had liver problems or jaundice?

○ Yes ◉ No

Have you ever had gastro-intestinal (bowel) or gallbladder problems?

○ Yes ◉ No

Do you have diabetes?

○ Yes ◉ No

Have you ever suffered from migraines?

○ Yes ◉ No

Do you have limited mobility e.g. are you a wheelchair user?

○ Yes ◉ No

Have you ever had an autoimmune disease such as systemic lupus erythematosus (SLE)?

○ Yes ◉ No

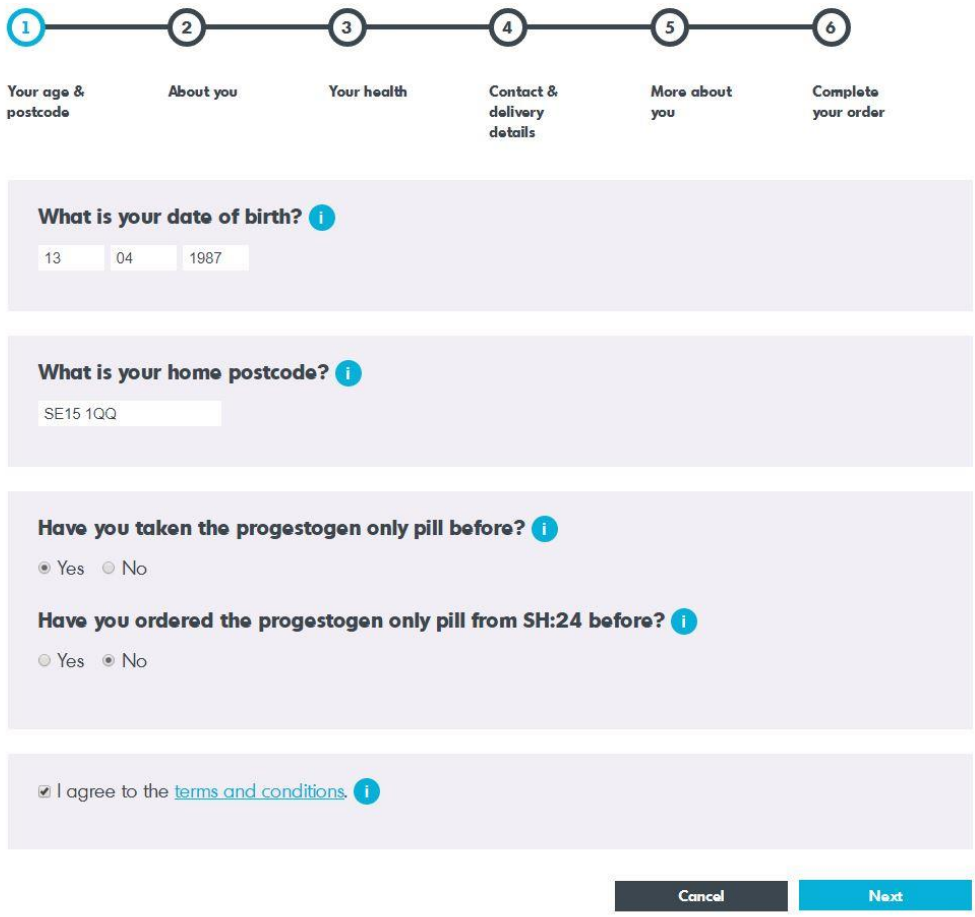
Have you ever had any other serious health conditions, illnesses, major surgery or medical treatment that we should know about?

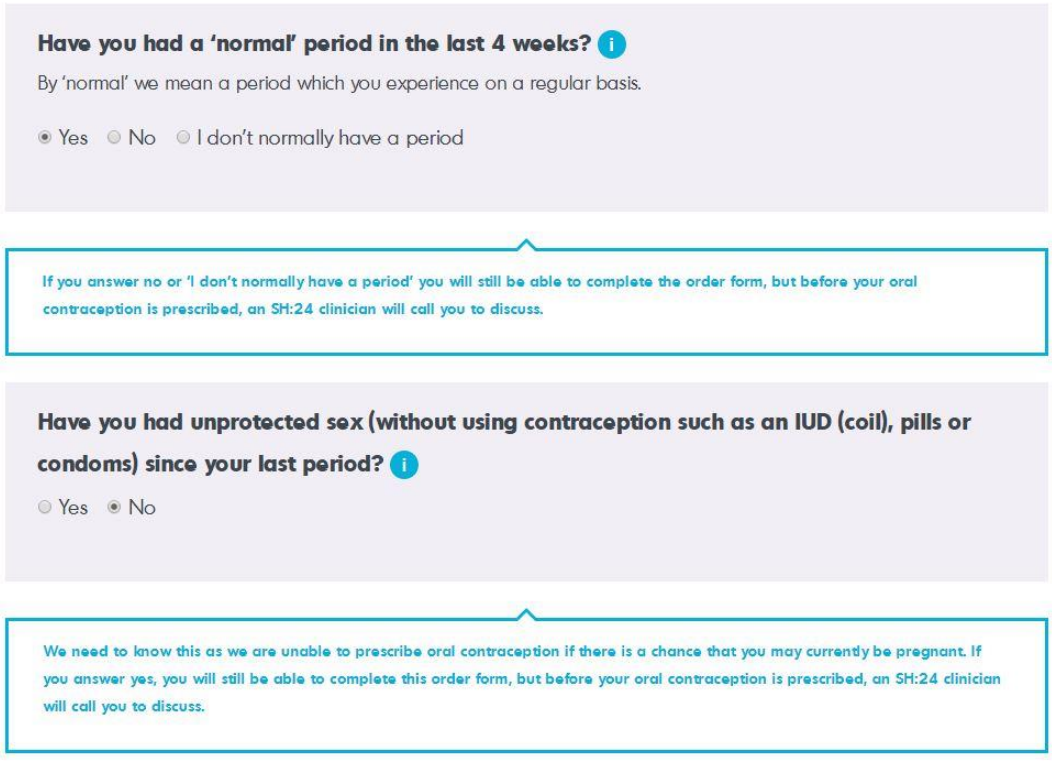
○ Yes ◉ No

Have you ever been told by a healthcare professional that the combined pill might not be suitable for you?

○ Yes ◉ No

9. Questions asked to service-users ordering POP





Are you allergic to progestogen?

○ Yes ◉ No

We need to know this as progestogen is the active ingredient in POP. If you answer yes, you will still be able to complete this order form, but before your oral contraception is prescribed, an SH:24 clinician will call you to discuss.

Are you allergic to lactose?

○ Yes ◉ No

We need to know this as lactose is often an ingredient of POP. If you answer yes, you will still be able to complete this order form, but before your oral contraception is prescribed, an SH:24 clinician will call you to discuss.

Previous Next

Has anyone in your close family (mother/father/brother/sister) had a blood clot, stroke or heart attack under the age of 50?

○ Yes ○ No

By family history we mean anyone in your immediate family under 45 years old; parent, grandparent, sibling or child, who has had blood clots, strokes, heart disease or heart attacks - this may include venous or arterial thrombosis, pulmonary embolus, transient ischaemic attacks (TIAs), hypertension or high cholesterol. We need to know this as the combined pill can cause an increased risk of blood clots. If you answer yes, you will still be able to complete this order form, but before your oral contraception is prescribed, an SH:24 clinician will call you to discuss

Are you taking prescription medications or the herbal medicine St John's Wort?

○ Yes ○ No

We need to know this as some prescription and herbal medicines can prevent the combined pill from working or cause other health complications. If you answer yes, you will still be able to complete this order form, but before your oral contraception is prescribed, an SH:24 clinician will call you to discuss.

Have you ever had breast cancer?

○ Yes ○ No

We need to know this as POP may further complicate this condition. If you answer yes, you will still be able to complete this order form, but before your oral contraception is prescribed, an SH:24 clinician will call you to discuss.

Have you ever had gastro-intestinal (bowel) or gallbladder problems?

○ Yes ○ No

We need to know this as gut conditions that cause malabsorption may prevent POP from working or cause other health complications. If you answer yes, you will still be able to complete this order form, but before your oral contraception is prescribed, an SH:24 clinician will call you to discuss.

Have you experienced any unusual vaginal bleeding in the last 2 years?

○ Yes ○ No

By 'unusual', we mean bleeding other than your normal period, or normal recovery after you've had a baby. We need to know this, even if you have had a diagnosis, as we need to understand the cause of this bleeding before you start taking oral contraception. If you answer yes, you will still be able to complete this order form, but before your oral contraception is prescribed, an SH:24 clinician will call you to discuss.

Have you ever had liver problems or jaundice?

○ Yes ○ No

We need to know this as POP can sometimes be unsuitable for those with serious liver conditions. If you answer yes, you will still be able to complete this order form, but before your oral contraception is prescribed, an SH:24 clinician will call you to discuss.

Have you ever had thrombosis (blood clots), a stroke or a heart condition?

○ Yes ○ No

We need to know this as oral contraception can cause an increased risk of blood clots. POP can sometimes be unsuitable for those who have had thrombosis, a stroke or a heart condition. If you answer yes, you will still be able to complete this order form, but before your oral contraception is prescribed, an SH:24 clinician will call you to discuss.

Have you ever had any other serious health conditions, illnesses, major surgery or medical treatment that we should know about?

○ Yes ○ No

To reduce the risk of any potential health complications arising when taking the progestogen only pill, we need to know of any other serious conditions, illnesses or medical interventions, including porphyria, systemic lupus erythematosus (SLE), arterial disease, coeliac disease, treatment for a hormone dependant cancer (e.g. breast, ovary, uterine, cervical or endometrial), functional ovarian cysts or complications in pregnancy (e.g. jaundice, ectopic pregnancy or trophoblastic disease).

Have you ever been told by a healthcare professional that the progestogen only pill might not be suitable for you?

○ Yes ○ No

To reduce the risk of any potential health complications which may arise when taking the progestogen only pill, we need to know if you have ever been advised not to take it by a healthcare professional. A clinician will call you to discuss.

Previous Next

Appendix D. Brief Survey Delivered to Participants of the CiP-CO Study at Data Collection Point One

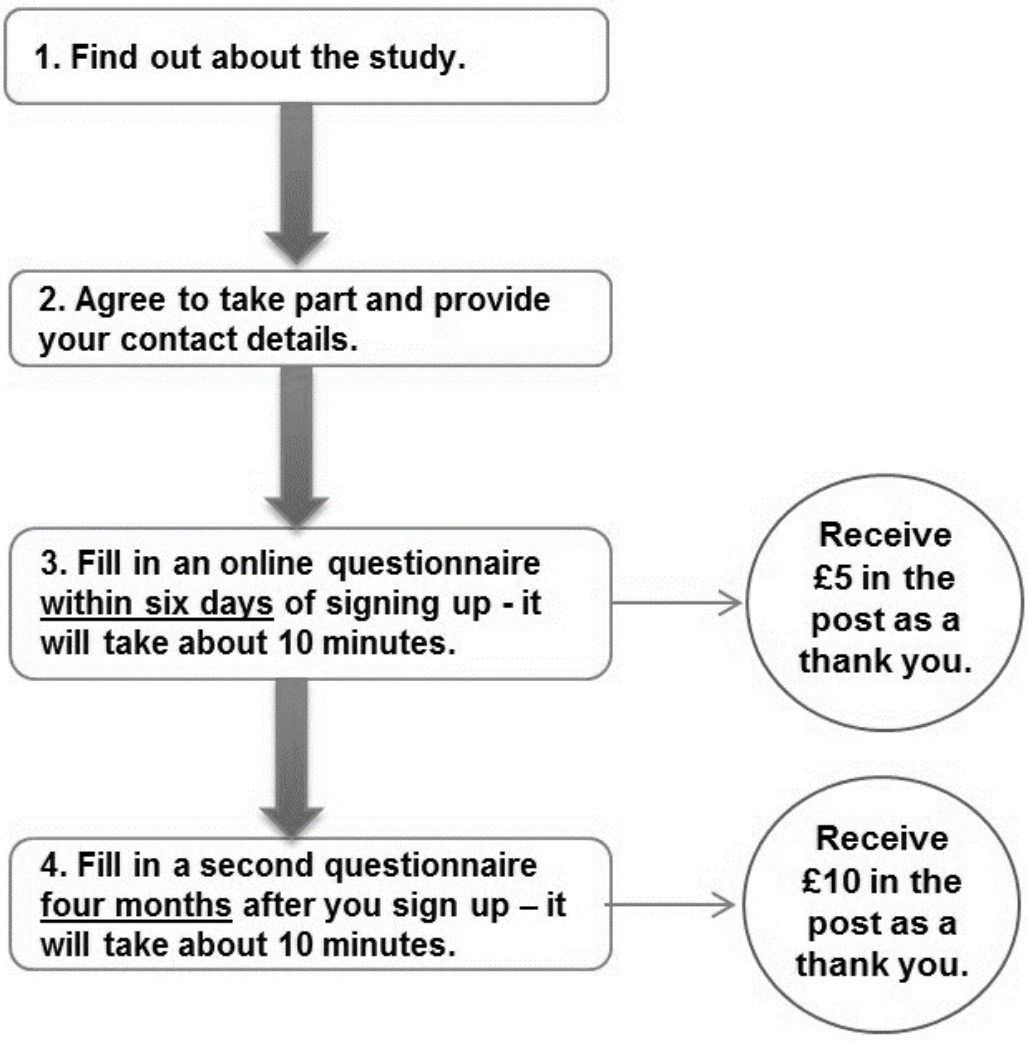
Welcome to the CiP-CO Study!

This study is run by researchers from King's College London working with the NHS.

We are finding out about how people access and experience contraception services in Lambeth and Southwark.

If you decide to sign up today, we will ask you to complete 2 online questionnaires, the first in 6 days (for which you will be sent £5) and the second in 4 months (for which you will be sent £10).

This flow chart explains what your participation will involve.



CLINIC NUMBER:

	Write answer here
1. **What is your full name (first name and surname)?**	
2. **What is your date of birth?**	__ __ / __ __ / __ __ __ __
3. **Address**	
4. **Postcode** **So that we can post you your £15 to thank you for taking part in the study**	
5. **Email**	
6. **Mobile phone number** **We will text you a link to the next questionnaire**	

Thank you for agreeing to participate in The CiP-CO study! We will send you the link to the first questionnaire in 6 days.

If you would like further information please contact:

Emma Rezel (Study Coordinator) or Dr Paula Baraitser (Chief Investigator), Global Health, King's College London, Cutcombe Street, London, SE5 9RJ. **Email:** emma.rezel@kcl.ac.uk **Tel:** 0207 848 5052

Appendix E. Questionnaire One Delivered to Participants of the CiP-CO Study at Data Collection Point Two

Questionnaire 1

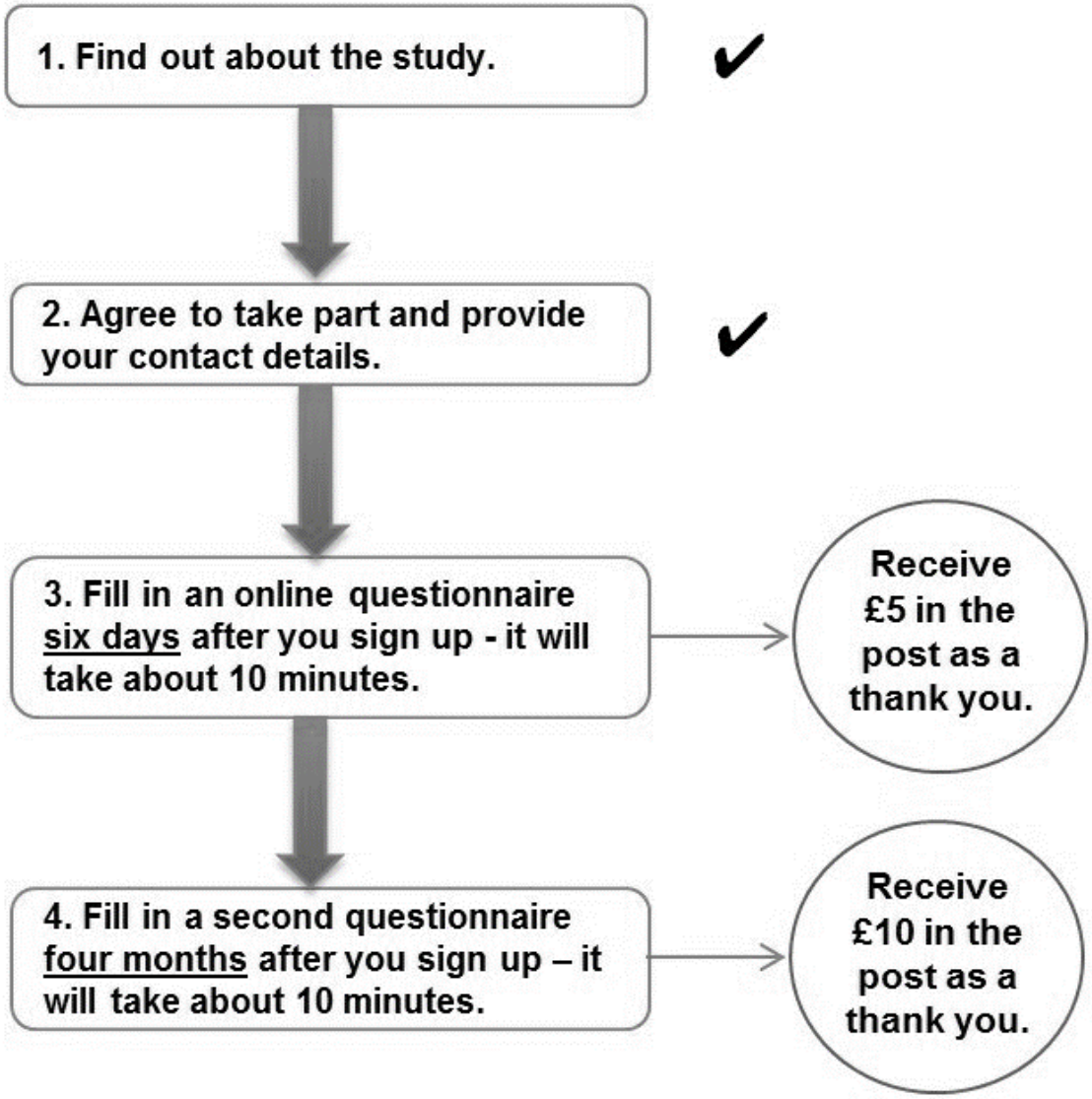
Welcome back to the CiP-CO Study!

The following questionnaire will take about 10 minutes to complete and all your answers will be kept separate from the contact details you gave us when you signed up.

We are finding out about how people access and experience contraception services in Lambeth and Southwark. It will help us learn how to maximise women's contraceptive choices and abilities to access contraception effectively.

This study is run by researchers from King's College London working with the NHS. If you would like further information please contact Emma Rezel (Study Coordinator)/ Dr Paula Baraitser (Chief Investigator), Global Health, King's College London, Cutcombe Street, London, SE5 9RJ.

You have reached stage 3 of the CiP-CO Study. This questionnaire will take about 10 minutes and then you will be posted £5.


1. Find out about the study.
✔
2. Agree to take part and provide your contact details.
✔
3. Fill in an online questionnaire six days after you sign up - it will take about 10 minutes.
Receive £5 in the post as a thank you.
4. Fill in a second questionnaire four months after you sign up – it will take about 10 minutes.
Receive £10 in the post as a thank you.

Sociodemographic Information

We will now ask you questions about your employment, education, ethnicity, relationship status and smoking. We ask everyone these questions because we want to see if the people in our study are similar to the general population of Lambeth and Southwark.

1. Which of the following best describes your employment status? ***Choose all that apply***		
	Tick the box	
a) Employed	☐	Go to Q2
b) Unemployed	☐	Go to Q3
c) Student	☐	Go to Q3
d) Parent or carer	☐	Go to Q3
e) Other (please state) _____	☐	Go to Q3

Only for those who ticked a) Employed for Q1 **2. Which of the following best describes your working hours?**		
	Tick the box	
a) Full-time	☐	Go to Q3
b) Part-time	☐	Go to Q3
c) Other (including flexible hours, on-call, zero hours and term time contract)	☐	Go to Q3

3. Which of the following best describes your ethnicity? ***This information will help us to see how closely our study population reflects the population of Lambeth and Southwark.***		
		Tick the box
- White:	English/Welsh/Scottish/Northern Irish/British	☐
	Irish	☐
	Gypsy or Irish Traveller	☐
	Any other White background	☐
- Mixed:	White and Black Caribbean	☐
	White and Black African	☐
	White and Asian	☐
	-Any other mixed background	☐
- Asian/Asian British:	Indian	☐
	Pakistani	☐
	Bangladeshi	☐
	Chinese	☐
	Any other Asian background/ Asian British	☐
- Black or Black British:	- Black or Black British: Caribbean	☐
	- Black or Black British: African	☐
	- Any other Black/African/Caribbean background/ Black British	☐
- Other Ethnic Group:	Arab	☐
	Latin American	☐
	Any other ethnic group	☐
	Not known	☐
	Prefer not to say	☐

4. What is the highest education level that you have reached or are currently studying for?	
	Tick the box
- No educational qualification	☐
- Entry level certificate	☐
- Entry level Skills for Life	☐
- Entry level award, certificate and diploma	☐
- Entry level Functional Skills	☐
- Entry level Foundation Learning	☐
- GCSE (grades D-G)	☐
- GCSE (grades A*-C)	☐

- Foundation Learning level 1	☐
- Key Skills level 1	☐
- Key Skills level 2	☐
- Key Skills level 3	☐
- Key Skills level 4	☐
- Functional Skills level 1	☐
- Functional Skills level 2	☐
- NVQ level 1	☐
- NVQ level 2	☐
- NVQ level 3	☐
- NVQ level 4	☐
- NVQ level 5	☐
- Skills for Life level 1	☐
- Skills for Life level 2	☐
- Foundation diploma	☐
- BTEC award, certificate and diploma level 1	☐
- BTEC award, certificate and diploma level 2	☐
- BTEC award, certificate and diploma level 3	☐
- BTEC National	☐
- BTEC Professional award, certificate and diploma level 4	☐
- BTEC Professional award, certificate and diploma level 5	☐
- BTEC Advanced Professional award, certificate and diploma level 6	☐
- BTEC Advanced Professional award, certificate and diploma level 7	☐
- Cambridge National level 1	☐
- Cambridge National level 2	☐
- Cambridge Technical level 2	☐
- Cambridge Technical level 3	☐
- Higher diploma	☐
- AS and A level	☐
- Advanced Extension Award	☐
- Cambridge International award	☐
- International Baccalaureate	☐
- Advanced diploma	☐
- Progression diploma	☐
- Certificate of higher education	☐
- HNC	☐
- HND	☐
- Higher diploma	☐

- Diploma of higher education	☐
- Diploma of further education	☐
- Foundation degree	☐
- Bachelor's degree	☐
- Graduate certificate	☐
- Graduate diploma	☐
- Fellowship and fellowship diploma	☐
- Postgraduate certificate	☐
- Postgraduate diploma	☐
- Master's degree	☐
- Postgraduate certificate	☐
- Postgraduate diploma	☐
- Vocational qualifications level 8	☐
- PhD/Doctorate	☐

5. Are you a smoker?	
	Tick the box
a) Yes	☐
b) No	☐

Current Contraceptive Information

We will now ask you some questions about your use of contraception.

6. Please select the name of the service you used for your most recent supply of contraception (that you accessed in the past few weeks).	
	Tick the box
a) Camberwell Sexual Health Centre	☐
b) Burrell Street Sexual Health Service	☐
c) Lloyd Clinic (at Guy's Hospital)	☐
d) Streatham Hill Sexual Health	☐
e) Walworth Road Clinic	☐
f) Brook Sexual Health Service for Young People	☐
g) GP (please state name and address)	☐
h) Other (please state) _____	☐

7. Please provide the date that you accessed this service
__ __ / __ __ / __ __ __ __

8. Is this the first time you have been given oral contraceptive pills?		
	Tick the box	
a) Yes	☐	Go to Q9
b) No	☐	Go to Q10

Only for those who ticked b) No for Q8 9. Please select one of the following statements that best describes your previous use of the pill	
	Tick the box
a) I have been taking oral contraceptive pills recently, i.e. at some point in the past year.	☐
b) I have not taken oral contraceptive pills in the past year but have taken them at some point in my life.	☐

10. What is your main reason for accessing the pill?	
	Tick the box
a) To prevent pregnancy.	☐
b) Another reason.	☐

Relationships

We will now ask you some questions about your relationships and reproductive and contraceptive history to get a picture of the circumstances surrounding your use of contraception. Don't forget that your answers will be kept confidential.

11. Are you sexually active? ***This means you have had sex in the past six months or are you planning to have sex soon.***	
	Tick the box
a) Yes	☐
b) No	☐

12. How many sexual partners have you had in the past year?	
	Put a number in the box
Please write a number in the box (put a 0 if you have had no sexual partners in the past year)	☐

13. Do you have a regular partner?	
	Tick the box
a) Yes	☐
b) No	☐

14. Have you ever been pregnant?		
	Tick the box	
a) Yes	☐	Go to Q15
b) No	☐	Go to Q16
Only for those who ticked a) Yes for Q14 **15. How many times have you been pregnant?**		
	Put a number in the box	
	☐	

16. Do you have children?		
	Tick the box	
a) Yes	☐	Go to Q17
b) No	☐	Go to Q18
Only for those who ticked a) Yes for Q16		
17. How many children do you have?		
	Put a number in the box	
	☐	

18. Have you ever had an abortion?		
	Tick the box	
a) Yes	☐	Go to Q19
b) No	☐	Go to Q20
Only for those who ticked a) Yes for Q18		
19. How many abortions have you had?		
	Put a number in the box	
	☐	

20. In the past year have you had unprotected sex at a time you did not want to be pregnant? *By "unprotected sex" we mean - did not use any form of contraception that would prevent pregnancy.*	
	Tick the box
a) Yes	☐
b) No	☐
c) Unsure	☐

21. In the past year have you taken emergency contraception? ***This is also known as the morning after pill. Emergency contraception can also include the emergency IUD or copper coil when inserted after sexual intercourse to prevent pregnancy.***	
	Tick the box
a) Yes	☐
b) No	☐

22. How likely do you think it is that you will use the pills you have been prescribed?					
	Very unlikely	Somewhat unlikely	Neutral neither likely or unlikely	Somewhat likely	Very likely
Tick the box	☐	☐	☐	☐	☐

23. If you keep taking the pill, how likely do you think it is that you would become pregnant during the next year?					
	Very unlikely	Somewhat unlikely	Neutral neither likely or unlikely	Somewhat likely	Very likely
Tick the box	☐	☐	☐	☐	☐

24. Below are a number of statements about how you might feel about becoming pregnant within the next year. Please select one that best describes how you might feel:	
	Tick the box
a) It would be the worst thing that could happen to me	☐
b) It would be very bad	☐
c) It would be sort of bad but not terrible	☐
d) It would be ok	☐
e) It would be sort of good but not terrific	☐
f) It would be very good	☐
g) It would be the best thing that ever happened to me	☐

25. Please indicate how the people who are most important to you would feel about your using the pill. Select the answer that best represents *their* feelings:	
	Tick the box
a) Very much opposed or not in favour of (would discourage use)	☐
b) Somewhat opposed or not in favour	☐
c) Neutral: neither opposed nor in favour of	☐
d) Somewhat in favour	☐
e) Very much in favour (would encourage use)	☐

Contraceptive Knowledge

The following questions are to find out how much knowledge you have about the pill. Please answer to the best of your ability; it doesn't matter if you get an answer wrong; we will give you the correct answers at the end.

26. Please state whether you think your pill is a progesterone only pill (POP) or a combined oral contraceptive pill (COC). ***The answer you select will allow us to ask you further knowledge questions that are specific to the type of pill you are taking.***			
		Tick the box	
a)	**Progesterone only pill (POP):** **The one that you take every day with no break between packets and is sometimes called the "mini-pill". Some common brands include Cerazette and Micronor etc.**	☐	Answer Q34 - Q38
b)	**Combined oral contraceptive pill (COC):** **The one that you take for three weeks and then have a seven day break, some common brands include Microgynon, Femodene and Cilest.**	☐	Answer Q27 - Q32
c)	**Unsure**	☐	Answer Q26 - Q32

Only for those who selected b) Combined oral contraceptive pill or c) Unsure to Q26	
27. You should see a doctor straight away if you experience which of the following side effects?	
	Tick the box
a) Breathlessness	☐
b) Painful swelling in your leg(s)	☐
c) Pain in the chest	☐
d) All of the above	☐
28. What effect will taking the pill have on your ability to have children in the future?	
	Tick the box
a) Your fertility will increase	☐
b) Your fertility will decrease	☐
c) There will be no effect	☐
d) The effect will depend on your age	☐
29. What effect will taking the pill have on your weight?	
	Tick the box
a) The pill will make your weight go up	☐
b) The pill will make your weight go down	☐
c) The pill will have no effect on your weight	☐
d) The effect will depend on your body weight and height	☐

Please read the following scenario then answer two questions about it:

SCENARIO 1: Carla went on holiday and missed 4 pills from her packet. When she came back she started taking her pills again as normal. She did not have sex while she was away but she is likely to have sex with her boyfriend now that she is back.

30. For how long will she need to use an additional form of contraception such as condoms to prevent getting pregnant?

	Tick the box
a) 2 days	☐
b) 5 days	☐
c) 7 days	☐
d) She should seek advice from a health service	☐

SCENARIO 1: Carla went on holiday and missed 4 pills from her packet. When she came back she started taking her pills again as normal. She did not have sex while she was away but she is likely to have sex with her boyfriend now that she is back.

31. There were only four more pills in her packet when she got back, what should do about her 7 day break?

	Tick the box
a) She should have her 7 day break as normal	☐
b) She should skip the break and start her new pill packet	☐
c) She should seek advice from a health service	☐
d) She should stop taking the pill	☐

Please read the following scenario then answer the question about it: ***SCENARIO 2: Bernadette went on holiday with Carla and missed 3 pills from her packet. She also had unprotected sex the night before she returned home.*** **32. Bernadette got back today, what should she do now?**	
	Tick the box
a) She should get emergency contraception	☐
b) She should not worry because her previous pill use will have protected her from pregnancy during this time	☐
c) She should take a pregnancy test right away	☐
d) She should wait and see if she has a period or not	☐
Please read the following scenario then answer the question about it: ***SCENARIO 3: Anne felt sick this morning and vomited once, half an hour after taking her pill.*** **33. Anne feels better in the afternoon and doesn't think she will vomit again. What should she do?**	
	Tick the box
a) Continue to take the pill as normal	☐
b) Take another pill immediately then continue as normal	☐
c) Stop taking her pill and re-start after her next period	☐
d) She should seek advice from a health service	☐

Here are the correct answers:

27) You should see a doctor straight away if you experience which of the following side effects?

The correct answer is **D) All of the above (breathlessness, painful swelling in your leg(s) and pain in the chest).**

28) What effect will taking the pill have on your ability to have children in the future?

The correct answer is **C) There will be no effect.**

29) What effect will taking the pill have on your weight?

The correct answer is **C) There will be no effect.**

SCENARIO 1: Carla went on holiday and missed 4 pills from her packet. When she came back she started taking her pills again as normal. She did not have sex while she was away but she is likely to have sex with her boyfriend now that she is back.

30. For how long will she need to use an additional form of contraception such as condoms to prevent getting pregnant?

The correct answer is **C) 7 days.** If you said D) She should seek advice from a health service - this is also a sensible option.

31. There were only four more pills in her packet when she got back, what should do about her 7 day break?

The correct answer is **B) she should skip the break and start her new pill packet.** If you said c) she should seek advice from a health service – this is also a sensible option.

SCENARIO 2: Bernadette went on holiday with Carla and missed 3 pills from her packet. She also had unprotected sex the night before she returned home.

32. Bernadette got back today, what should she do now?

The correct answer is **A) she should get emergency contraception.**

SCENARIO 3: Anne felt sick this morning and vomited once, half an hour after taking her pill.

33. Anne feels better in the afternoon and doesn't think she will vomit again. What should she do?

The correct answer is **b) take another pill immediately and continue as normal.** If you said d) she should seek advice from a health service, this is also a sensible option.

Only for those who selected a) Progesterone only pill to Q26	
34. How might your bleeding patterns change when you start taking the pill?	
	Tick the box
a) Bleeding may become irregular	☐
b) Bleeding may become lighter or stop altogether	☐
c) Bleeding may last longer	☐
d) It could be any of the above	☐
35. What effect will taking the pill have on your ability to have children in the future?	
	Tick the box
a) Your fertility will increase	☐
b) Your fertility will decrease	☐
c) There will be no effect	☐
d) The effect will depend on your age	☐
36. What effect will taking the pill have on your weight?	
a) The pill will make your weight go up	**Tick the box**
b) The pill will make your weight go down	☐
c) The pill will have no effect on your weight	☐
d) The effect will depend on your body weight and height	☐
e) She should seek advice from a health service	☐

Please read the following scenario then answer the question about it: ***SCENARIO 1: Carla went on holiday and missed 4 pills from her packet. When she came back she started taking her pills again as normal. She did not have sex while she was away but she is likely to have sex with her boyfriend now that she is back.*** **37. For how long will she need to use an additional form of contraception such as condoms to prevent getting pregnant?**	
	Tick the box
a) 2 days	☐
b) 5 days	☐
c) 7 days	☐
d) She should seek advice from a health service	☐
Please read the following scenario then answer the question about it: ***SCENARIO 2: Bernadette went on holiday with Carla and missed 3 pills from her packet. She also had unprotected sex the night before she returned home.*** **38. Bernadette got back today, what should she do now that she's home?**	
	Tick the box
a) She should get emergency contraception	☐
b) She should not worry because her previous pill use will have protected her from pregnancy during this time	☐
c) She should take a pregnancy test right away	☐
d) She should wait and see if she has a period or not	☐

Please read the following scenario then answer the question about it: *SCENARIO 3: Anne felt sick this morning and vomited once, half an hour after taking her pill.* **39. Anne feels better in the afternoon and doesn't think she will vomit again. What should she do?**	
	Tick the box
a) Continue to take the pill as normal	☐
b) Take another pill immediately then continue as normal	☐
c) Stop taking her pill and re-start after her next period	☐
d) She should seek advice from a health service	☐

Here are the correct answers:

34) How might your bleeding pattern change when you stop taking the pill?

The correct answer is **D) It could be any of the above (bleeding may become irregular, lighter or stop altogether or may last longer).**

35) What effect will taking the pill have on your ability to have children in the future?

The correct answer is **C) There will be no effect.**

36) What effect will taking the pill have on your weight?

The correct answer is **C) There will be no effect.**

SCENARIO 1: Carla went on holiday and missed 4 pills from her packet. When she came back she started taking her pills again as normal. She did not have sex while she was away but she is likely to have sex with her boyfriend now that she is back.

37. For how long will she need to use an additional form of contraception such as condoms to prevent getting pregnant?

The correct answer is **C) 2 days.** If you said D) She should seek advice from a health service - this is also a sensible option.

SCENARIO 2: Bernadette went on holiday with Carla and missed 3 pills from her packet. She also had unprotected sex the night before she returned home.

38. Bernadette got back today, what should she do now?

The correct answer is **A) she should get emergency contraception.**

SCENARIO 3: Anne felt sick this morning and vomited once, half an hour after taking her pill.

39. Anne feels better in the afternoon and doesn't think she will vomit again. What should she do?

The correct answer is **b) take another pill immediately and continue as normal.** If you said d) she should seek advice from a health service, this is also a sensible option.

Service Feedback

Please tell us to what extent you agree with the following statements about the service from which you accessed for your most recent supply of oral contraceptive pills.

Don't forget that your answers will be kept confidential.

40. Read statement	**Tick the extent to which you agree with the statement**				
	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
a) I did not have enough privacy when using this service.	☐	☐	☐	☐	☐
b) It was convenient to access the pill from this service.	☐	☐	☐	☐	☐
c) It would be easy to ask questions or communicate with the service if I had any problems with my contraception over the next three months.	☐	☐	☐	☐	☐
d) Getting oral contraceptive pills from this service was too slow.	☐	☐	☐	☐	☐
e) I received all the information that I needed from this service.	☐	☐	☐	☐	☐
f) This service limited my contraceptive choices.	☐	☐	☐	☐	☐

Thank you for finishing the first CiP-CO questionnaire! You will receive £5 in the post shortly and in four months we'll contact you to ask about your use of contraception.

If you would like further information please contact:

Emma Rezel (Study Coordinator) or Dr Paula Baraitser (Chief Investigator), Global Health, King's College London, Cutcombe Street, London, SE5 9RJ.

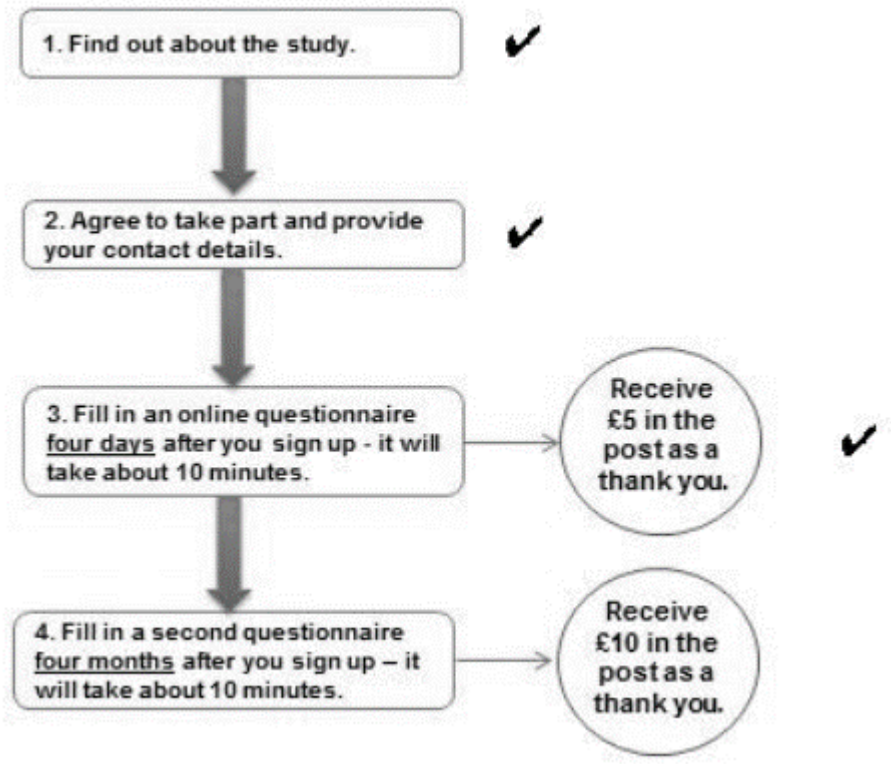
This is the end of the first questionnaire.

Appendix F. Questionnaire Two Delivered to Participants of the CiP-CO Study at Data Collection Point Three

Welcome back to the CiP-CO Study!

The following questionnaire will take about 10 minutes to complete and all your answers will be kept separate from the contact details you gave us when you signed up.
We are finding out how people access and experience contraception services in Lambeth and Southwark. It will help us learn how to maximise women's contraceptive choices and abilities to access contraception effectively.
When you have completed this questionnaire, we will send you the remaining £10 as a thank you for your time.
This study is run by researchers from King's College London working with the NHS.

Thank you for taking the time to take part. If you would like further information please contact Emma Rezel (Study Coordinator) or Dr Paula Baraitser (Chief Investigator), Global Health, King's College London, Cutcombe Street, London, SE5 9RJ. Email: emma.rezel@kcl.ac.uk Tel - 0207 848 5052
Thank you for taking part in the CiP-CO Study! It will take 10 minutes to complete this final stage and then we will send you £10 in the post.



1.	**Did you finish the supply of pills you accessed when you signed up to this study 4 months ago?**		
		Tick the box	
a)	**Yes**	☐	Go to Q9
b)	**No**	☐	Go to Q2

	Only for those who ticked b) No for Q1		
2.	**Please select the statement that best describes your use of the pills you accessed four months ago.**		
		Tick the box	
a)	**I started taking them but then I stopped**	☐	Go to Q3
b)	**I did not take any of these pills**	☐	Go to Q3
c)	**I am still taking them now**	☐	Thank you for your responses. As you are still taking your pills, it's too early for you to complete the final questionnaire. One of the CiP-CO researchers will call you shortly to reschedule. If you would like further information please contact Emma Rezel (Study Coordinator)/ Dr Paula Baraitser (Chief Investigator), Global Health, King's College London, Cutcombe Street, London, SE5 9RJ.

	Only for those who ticked a) I started taking them but then I stopped or b) I did not take any of these pills		
	3. Please select the statement that best describes your reason for this.		
		Tick the box	
a)	**I was concerned about the side effects of the pill**	☐	Go to Q6
b)	**I started a different type of contraception**	☐	Go to Q4
c)	**I was dissatisfied with the contraceptive service**	☐	Go to Q6
d)	**I am not currently sexually active**	☐	Go to Q6
e)	**Other** _____ _____ _____	☐	Go to Q6

	Only for those who ticked c) I started taking a different type of contraception		
	4. Please select a type of contraception		
		Tick the box	
a)	**Contraceptive Implant**	☐	Go to Q5
b)	**Intrauterine Device (IUD), coil**	☐	Go to Q5
c)	**Intrauterine System (IUS)**	☐	Go to Q5
d)	**Contraceptive injection**	☐	Go to Q5
e)	**Diaphragm**	☐	Go to Q5
f)	**Cap**	☐	Go to Q5
g)	**Natural Family Planning**	☐	Go to Q5
h)	**Sterilisation**	☐	Go to Q5
i)	**Contraceptive patch**	☐	Go to Q5
j)	**Vaginal ring**	☐	Go to Q5
k)	**Condoms (male or female)**	☐	Go to Q7

	Only for those who ticked a) to j) for Q4 **5. Are you still using this form of contraception now?**		
		Tick the box	
a)	**Yes**	☐	Go to Q20
b)	**No**	☐	Go to Q6

	Only for those who ticked b) No for Q5 **6. Are you using any form of contraception now?**		
		Tick the box	
a)	**Yes**	☐	Go to Q8
b)	**No**	☐	Go to Q24

	Only for those who ticked k) condoms for Q4 **7. Are you still using condoms now?**		
		Tick the box	
a)	**Yes**	☐	Go to Q22
b)	**No**	☐	Go to Q6

	Only for those who ticked a) Yes to Q6		
8.	**Please select a type of contraception**		
		Tick the box	
a)	**Contraceptive Implant**	☐	Go to Q20
b)	**Intrauterine Device (IUD), coil**	☐	Go to Q20
c)	**Intrauterine System (IUS)**	☐	Go to Q20
d)	**Contraceptive injection**	☐	Go to Q20
e)	**Diaphragm**	☐	Go to Q20
f)	**Cap**	☐	Go to Q20
g)	**Natural Family Planning**	☐	Go to Q20
h)	**Oral Contraceptive Pill**	☐	Go to Q20
i)	**Sterilisation**	☐	Go to Q20
j)	**Contraceptive patch**	☐	Go to Q20
k)	**Vaginal ring**	☐	Go to Q20
l)	**Condoms (male or female)**	☐	Go to Q22

	Only for those who ticked a) Yes for Q1		
9.	**Did you get more of the same type of pills when they had run out?**		
		Tick the box	
a)	**Yes**	☐	Go to Q11
b)	**No**	☐	Go to Q10

	Only for those who ticked b) No for Q9 **10. Did you get more pills but a different type or brand to the ones you had accessed before?**		
		Tick the box	
a)	**Yes**	☐	Go to Q11
b)	**No**	☐	Go to Q17

	11. Please select the name of the service you used for your most recent supply of contraception.		
		Tick the box	
a)	**Camberwell Sexual Health Centre**	☐	Go to Q12
b)	**Burrell Street Sexual Health Service**	☐	Go to Q12
c)	**Lloyd Clinic (at Guy's Hospital)**	☐	Go to Q12
d)	**Streatham Hill Sexual Health**	☐	Go to Q12
e)	**Walworth Road Clinic**	☐	Go to Q12
f)	**Brook Sexual Health Service for Young People**	☐	Go to Q12
g)	**SH:24**	☐	Go to Q12
h)	**I paid for contraception using an online service**	☐	Go to Q12
i)	**GP (please state name and address)** _____ _____ _____	☐	Go to Q12
j)	**Other (please state)** _____ _____	☐	Go to Q12

12. Is this the same service you used for the supply of pills you accessed four months ago?

	Tick the box	
a) Yes	☐	Go to Q14
b) No	☐	Go to Q13

Only for those who ticked b) No for Q12

13. Why did you switch to a different service?
Choose all that apply

	Tick the box	
a) It was more private	☐	Go to Q14
b) It was more convenient	☐	Go to Q14
c) To make it easier to communicate with the contraception provider	☐	Go to Q14
d) It was quicker	☐	Go to Q14
e) To get more information	☐	Go to Q14
f) Other (please state) _____ _____	☐	Go to Q14

14. Did you start your new pills late i.e. did you have a gap or delay in between accessing your first and second supply of pills?

For COC-users a delay is defined as not starting a new pack after the seven day break and for POP-users a delay is defined as not starting a new pack the day after the previous pack ran out.

Combined oral contraceptive pill (COC): The one that you take for three weeks and then have a seven day break, some common brands include Microgynon, Femodene and Cilest.
Progesterone only pill (POP): The one that you take every day with no break between packets, some common brands include Cerazette and Micronor.

	Tick the box	
a) Yes	☐	Go to Q15
b) No	☐	Go to Q16

Only for those who ticked a) Yes to Q14 **15. Did you have any unprotected sex during this time?** ***By unprotected sex we mean - did not use any form of contraception that would prevent pregnancy***		
	Tick the box	
a) Yes	☐	Go to Q16
b) No	☐	Go to Q16

Only for those who ticked b) No to Q15 **16. Did you have any other issues with your pills that you think may have put you at risk of pregnancy, such as missing pills?**		
	Tick the box	
a) Yes	☐	Go to Q28
b) No	☐	Go to Q32

17. Did you have any other issues with your pills that you think may have put you at risk of pregnancy, such as missing pills? ***For COC-users a delay is defined as not starting a new pack after the seven day break and for POP-users a delay is defined as not starting a new pack the day after the previous pack ran out***		
	Tick the box	
a) Yes	☐	Go to Q28
b) No	☐	Go to Q28

Only for those who tick b) No to Q10 **18. Did you switch to another type of contraception?**		
	Tick the box	
a) Yes	☐	Go to Q19
b) No	☐	Go to Q24

	Only for those who ticked a) Yes to Q17 **19. Please select a type of contraception**		
		Tick the box	
a)	**Contraceptive Implant**	☐	Go to Q20
b)	**Intrauterine Device (IUD), coil**	☐	Go to Q20
c)	**Intrauterine System (IUS)**	☐	Go to Q20
d)	**Contraceptive injection**	☐	Go to Q20
e)	**Diaphragm**	☐	Go to Q20
f)	**Cap**	☐	Go to Q20
g)	**Natural Family Planning**	☐	Go to Q20
h)	**Sterilisation**	☐	Go to Q20
i)	**Contraceptive patch**	☐	Go to Q20
j)	**Vaginal ring**	☐	Go to Q20
k)	**Condoms (male or female)**	☐	Go to Q21

	Only for those who ticked anything from a) to j) in Q19 **20. Why did you switch to this type of contraception?** ***Choose all that apply***		
		Tick the box	
a)	**I was concerned about the side effects of the pill**	☐	Go to Q21
b)	**I wanted a more effective form of contraception**	☐	Go to Q21
c)	**I wanted a more permanent form of contraception**	☐	Go to Q21
d)	**I wanted a non-hormonal method of contraception**	☐	Go to Q21
e)	**I was dissatisfied with the contraceptive service I used at the start of the study**	☐	Go to Q21
f)	**Other (please state)** _____ _____	☐	Go to Q21

21. Please select the name of the service you used for this supply of contraception.		
	Tick the box	
a) Camberwell Sexual Health Centre	☐	Go to Q25
b) Burrell Street Sexual Health Service	☐	Go to Q25
c) Lloyd Clinic (at Guy's Hospital)	☐	Go to Q25
d) Streatham Hill Sexual Health	☐	Go to Q25
e) Walworth Road Clinic	☐	Go to Q25
f) Brook Sexual Health Service for Young People	☐	Go to Q25
g) SH:24	☐	Go to Q25
h) I paid for contraception using an online service	☐	Go to Q25
i) GP (please state name and address) _____ _____ _____	☐	Go to Q25
j) Other (please state) _____	☐	Go to Q25

	Only for those who ticked anything from k) condoms in Q18 **22. Why have you decided to use condoms?** ***Choose all that apply***		
		Tick the box	
a)	**I was concerned about the side effects of the pill**	☐	Go to Q23
b)	**I wanted to use a non-hormonal form of contraception**	☐	Go to Q23
c)	**I am not having regular sex**	☐	Go to Q23
d)	**I wanted to protect myself from sexually transmitted infections**	☐	Go to Q23
e)	**I am not worried about getting pregnant**	☐	Go to Q23
f)	**I find it easier/more convenient to use condoms**	☐	Go to Q23
g)	**I was dissatisfied with the contraceptive service I used at the start of the study**	☐	Go to Q23
h)	**Other (please state)** **_____** **_____**	☐	Go to Q23

23. Please select the service from which you got condoms		
	Tick the box	
a) Camberwell Sexual Health Centre	☐	Go to Q25
b) Burrell Street Sexual Health Service	☐	Go to Q25
c) Lloyd Clinic (at Guy's Hospital)	☐	Go to Q25
d) Streatham Hill Sexual Health	☐	Go to Q25
e) Walworth Road Clinic	☐	Go to Q25
f) Brook Sexual Health Service for Young People	☐	Go to Q25
g) GP (please state name and address) _____ _____ _____	☐	Go to Q25
h) I bought condoms from a shop or a private online service	☐	Go to Q25
i) Freedoms Shop	☐	Go to Q25
j) Other (please state) _____	☐	Go to Q25

Only for those who tick b) No to Q6 or b) No to Q17

24. You state that you have stopped using any form of contraception – what was the reason for this?

Please select as many of the following statements as are applicable:

		Tick the box	
a)	**I was concerned about side effects of contraception**	☐	Go to Q27
b)	**I was dissatisfied with the contraception service**	☐	Go to Q27
c)	**I decided I would prefer to use withdrawal**	☐	Go to Q27
d)	**I decided I would probably use condoms if or when I have sex**	☐	Go to Q27
e)	**I stopped in order to become pregnant**	☐	Go to Q27
f)	**I stopped because I don't mind if I become pregnant or not**	☐	Go to Q27
g)	**I stopped because I was pregnant**	☐	Go to Q27
h)	**I am not currently sexually active**	☐	Go to Q27
i)	**Other (please state)** _____	☐	Go to Q27

25. Is this the same service you used for the supply of pills you accessed four months ago?		
	Tick the box	
a) Yes	☐	Go to Q27
b) No	☐	Go to Q26

Only for those who ticked b) No for Q26 26. Why did you switch to a different service? *Choose all that apply*		
	Tick the box	
a) It was more private	☐	Go to Q27
b) It was more convenient	☐	Go to Q27
c) To make it easier to communicate with the contraception provider	☐	Go to Q27
d) It was quicker	☐	Go to Q27
e) To get more information	☐	Go to Q27
f) Other (please state) _____ _____	☐	Go to Q27

27. Have you had any unprotected sex since you enrolled in the study, i.e. in the past four months? *By unprotected sex we mean – did not use any form of contraception that would prevent pregnancy*		
	Tick the box	
a) Yes	☐	Go to Q28
b) No	☐	Go to Q32
c) Unsure	☐	Go to Q28

28. What did you do about any potential risks of pregnancy (or any other issues with your contraception) since you began this study four months ago?		
	Tick the box	
a) I took no action	☐	Go to Q32
b) I asked a friend	☐	Go to Q31
c) I used the internet	☐	Go to Q31
d) I got advice from the service that I used to get contraception	☐	Go to Q30
e) I got advice from a different service	☐	Go to Q29
f) I used a leaflet	☐	Go to Q31
g) Other (please state) _____ _____	☐	Go to Q31

29. Please select the service from which you got advice		
	Tick the box	
a) Camberwell Sexual Health Centre	☐	Go to Q30
b) Burrell Street Sexual Health Service	☐	Go to Q30
c) Lloyd Clinic (at Guy's Hospital)	☐	Go to Q30
d) Streatham Hill Sexual Health	☐	Go to Q30
e) Walworth Road Clinic	☐	Go to Q30
f) Brook Sexual Health Service for Young People	☐	Go to Q30
g) A private online service	☐	Go to Q30
h) A private clinic	☐	Go to Q30
i) GP (please state name and address) _____ _____ _____	☐	Go to Q30
j) SH:24	☐	Go to Q30
k) Other (please state) _____	☐	Go to Q30

30. How did you communicate with the service?		
	Tick the box	
a) I texted them	☐	Go to Q31
b) I called them	☐	Go to Q31
c) I attended the service	☐	Go to Q31
d) I used webchat	☐	Go to Q31
e) Other (please state) _____	☐	Go to Q31

31. Was this helpful?		
	Tick the box	
a) Yes	☐	Go to Q32
b) No	☐	Go to Q32
c) Other (please state) _____	☐	Go to Q32

32. Please provide any additional comments about the CiP-CO study.
Write your answer below

33. Please provide any additional comments about contraception services in Lambeth and Southwark?
Write your answer below

34. Would you be happy to be contacted by this King's College London research group about future studies? ***Your response does not affect your participation in the CiP-CO study.***	
	Tick the box
a) Yes	☐
b) No	☐

Thank you.

You will receive £10 in the post as a thank you for completing the final questionnaire.

Appendix G. Crude and adjusted odds ratios of OCP continuation by exposure (type of service) (n=121[†])

	Crude OR (95% CI)[a]	p value	Adjusted OR (95% CI)[b]	p value	Adjusted OR (95% CI)[c]	p value
Exposure						
Other services	1 (ref)	-	1 (ref)	-	1 (ref)	
Online contraception	2.56 (1.18 – 5.57)	0.018*	3.13 (1.28 – 7.65)	0.012*	2.93 (1.17 – 7.37)	0.022*
Age group (years)						
16 – 19	0.38 (0.13 – 1.13)	0.082	0.32 (0.08 – 1.35)	0.121	0.28 (0.62 – 1.27)	0.098
20 – 24	1 (ref)	-	1 (ref)		1 (ref)	
25 - 29	0.55 (0.21 – 1.45)	0.227	0.39 (0.12 – 1.29)	0.123	0.39 (0.12 – 1.29)	0.122
30+	0.99 (0.34 – 2.87)	0.990	1.25 (0.31 – 5.02)	0.756	1.34 (0.32 – 5.15)	0.690
Ethnic Group						
White	1 (ref)	-	1 (ref)	-	1 (ref)	-
Black	0.34 (0.12 – 0.93)	0.036*	0.22 (0.07 – 0.73)	0.013*	0.22 (0.07 – 0.72)	0.012*
Asian	0.81 (0.19 – 3.44)	0.778	0.68 (0.13 – 3.50)	0.645	0.64 (0.12 – 3.39)	0.604
Mixed	0.20 (0.04 – 1.05)	0.057	0.25 (0.05 – 1.40)	0.115	0.27 (0.05 – 1.55)	0.142
Other	5.00 (0.52 – 48.54)	0.165	5.70 (0.53 – 61.51)	0.152	4.44 (0.40 – 48.97)	0.223
IMD						
1st quintile (most deprived)	1 (ref)	-	1 (ref)	-	1 (ref)	-
2nd quintile	1.00 (0.44 – 2.27)	0.999	1.18 (0.43 – 3.24)	0.745	1.35 (0.47 – 3.85)	0.575
3rd quintile	0.53 (0.16 – 1.80)	0.308	1.15 (0.26 – 4.99)	0.852	1.23 (0.28 – 5.46)	0.787
4th quintile	0.73 (0.12 – 4.51)	0.731	1.23 (0.14 – 10.71)	0.849	1.29 (0.13 – 12.54)	0.831
5th quintile (least deprived)	-[††]	-	-[††]	-	-[††]	
Employment status						
Employed	1 (ref)	-	1 (ref)	-	1 (ref)	-
Unemployed	2.21 (0.47 – 10.47)	0.317	2.26 (0.38 – 13.36)	0.368	2.06 (0.34 – 12.59)	0.432
Student	0.72 (0.32 – 1.65)	0.440	0.81 (0.28 - 2.36)	0.703	0.78 (0.27 – 2.28)	0.655
Student & Employed	1.63 (0.41 – 6.43)	0.638	2.61 (0.14 – 10.71)	0.298	2.35 (0.38 – 14.69)	0.360
Education level						
Entry Level – Level 2	0.56 (0.15 – 2.12)	0.397	0.52 (0.11 – 2.39)	0.399	0.56 (0.12 – 2.67)	0.464
Level 3 - 5	0.89 (0.39 – 2.05)	0.791	1.23 (0.40 – 3.82)	0.720	1.42 (0.44 – 4.59)	0.555
Level 6 - 8	1 (ref)	-	1 (ref)	-	1 (ref)	-
Smoking status						
Smoker	0.54 (0.22 – 1.32)	0.177	-	-	0.56 (0.20 – 1.57)	0.270
Likelihood that OCPs prescribed will be taken						
Unlikely	0.64 (0.11 – 3.54)	0.607	-	-	0.59 (0.08 – 4.25)	0.603
Neutral	1.11 (0.24 – 5.07)	0.890	-	-	1.48 (0.24 – 9.23)	0.674
Likely	1 (ref)	-	-	-	1 (ref)	0.913

Confidence interval, CI; odds ratio, OR; index of multiple deprivation, IMD; oral contraceptive pills, OCPs

*p value significant <0.05
†Further reduction in sample size from primary outcome data (Table 6-5) due to missing data from self-reported questionnaire at 6 days post recruitment (online contraception n=40; other services n=81)
††No observations for IMD in the 5th quintile
[a]Adjusted for exposure
[b]Adjusted for exposure; age group; ethnic group; IMD quintile; employment status; education level
[c]Adjusted for exposure; age group; ethnic group; IMD quintile; employment status; education level; smoking status; likelihood that OCPs prescribed will be taken

Appendix H. Invitation email to prospective participants of the theory of change study qualitative study

Dear [Insert name of prospective participant here]

I would like to invite you to participate in a research study that will explore the impact of online contraceptive health services on the population of Lambeth and Southwark. You are under no obligation to reply to this email, however if you do choose to reply, participation in this research is voluntary and you may withdraw at any time.

Participation in this study would involve a tape recorded interview lasting up to 1 hour that will focus on how online contraceptive health services may or may not lead to improved contraceptive provision of the specified population. The interviews would be arranged at the time convenient to you and conducted in a private room by one of the research staff involved in the project.

The results of this work will improve our understanding of how such services might work and will feed directly into new service development both locally and further afield.

The information sheet (attached) will give more information about the interview and the study.

If you wish to participate in this study or have any questions about participation then please contact me.

King regards

Emma Rezel

Appendix I. Participant Information Sheet for theory of change qualitative study

INFORMATION SHEET FOR PARTICIPANTS

REC Reference Number: ***BDM/13/14-42****.*

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Understanding how and why online sexual health services might be an effective alternative to clinic based care.

We would like to invite you to participate in this original research project. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation 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.

This research aims to identify how and why online sexual health services may meet or fail to meet the needs of the people of Lambeth and Southwark. This work will then inform the development and implementation of online sexual health services.

This project is funded by the Guys and St Thomas' Charity.

We are recruiting key stakeholders for this project, for example those who might commission, develop or provide such services and those who might use them.

Those who agree to take part will be contacted to arrange a single interview that will last for up to 1 hour. The interview can take part at Kings College London or a mutually convenient location.

The interviews will focus on respondents views in general on online sexual health services and not individual experience, however if respondents identify a need for any sexual health information or advice they will be referred to local services.

Interviews will be identified by a code number only and not your name. We will hold the interviews in a secure place within Kings College London and in accordance with the UK Data Protection Act and only the research team will have access to your interviews. We may use

anonymous quotes and will ensure that no material that can identify you in any way will be included in any reports or publications from this work.

We plan to share the information from this research as a peer reviewed publication and as a report to those planning the development of online sexual health services locally.

If you agree to take part you will be asked whether you are happy to be contacted about participation in future studies. Your participation in this study will not be affected should you choose not to be re-contacted.

Interviews will be recorded, subject to your permission. Recordings of interviews will be deleted within 10 days of transcription.

If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form.

It is up to you to decide whether to take part or not. If you decide to take part you are still free to withdraw from the study at any time and without giving a reason. If you participate, you can withdraw your data up until the 12th March 2015 through contacting Emma Rezel at emma.rezel@kcl.ac.uk

If you have any questions or require more information about this study, please contact the researcher using the following contact details: Emma Rezel, Kings College London, HIV & Sexual Health Research, Weston Education centre, 10 Cutcombe Road, London, SE5 9RJ or email:

emma.rezel@kcl.ac.uk

If this study has harmed you in any way, you can contact King's College London using the details below for further advice and information: Dr Paula Baraitser, Senior Lecturer, Kings College London, HIV & Sexual Health Research, Weston Education centre, 10 Cutcombe Road, London, SE5 9RJ or email: paula.baraitser@kcl.ac.uk

Appendix J. Consent form for theory of change qualitative study

CONSENT FORM FOR PARTICIPANTS IN RESEARCH STUDIES

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of Study: Understanding how and why online sexual health services might be an effective alternative to clinic based care.

King's College Research Ethics Committee Ref: ***BDM/13/14-42.***

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

Please tick or initial	
☐	**I understand that if I decide at any time during the research that I no longer wish to participate in this project, I can notify the researchers involved and withdraw from it immediately without giving any reason. Furthermore, I understand that I will be able to withdraw my data at any time up until the 12th March 2015.**
☐	**I consent to the processing of my personal information for the purposes explained to me. I understand that such information will be handled in accordance with the terms of the UK Data Protection Act 1998.**

• The information you have submitted will be published as a report; please indicate whether you would like to receive a copy.

Yes	No

• I understand that confidentiality and anonymity will be maintained and it will not be possible to identify me in any publications

Yes	No

• I agree to be contacted in the future by King's College London researchers who would like to invite me to participate in follow up studies to this project, or in future studies of a similar nature.

Yes	No

• I consent to my interview being audio recorded.

Yes	No

Participant's Statement:

I _____

agree that the research project named above has been explained to me to my satisfaction and I agree to take part in the study. I have read both the notes written above and the Information Sheet about the project, and understand what the research study involves.

Signed **Date**

Investigator's Statement:

I _____

Confirm that I have carefully explained the nature, demands and any foreseeable risks (where applicable) of the proposed research to the participant.

Signed **Date**

Appendix K. Previous iterations of theory of change conceptual models

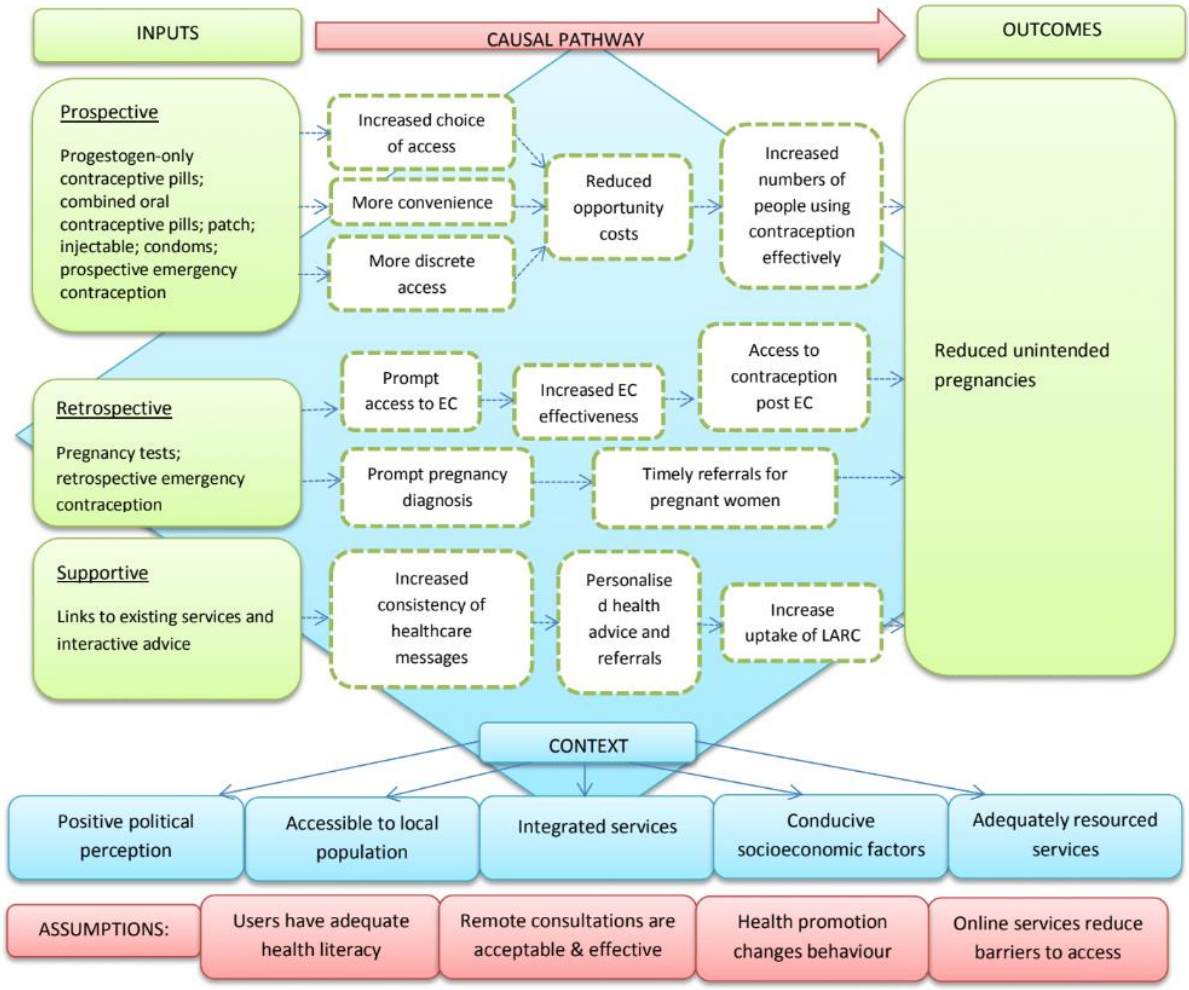


Figure 1 Theory of change diagram based on the SH:24 funding application and original stakeholder interview. Presents only the positive causal pathways leading to beneficial public health outcomes

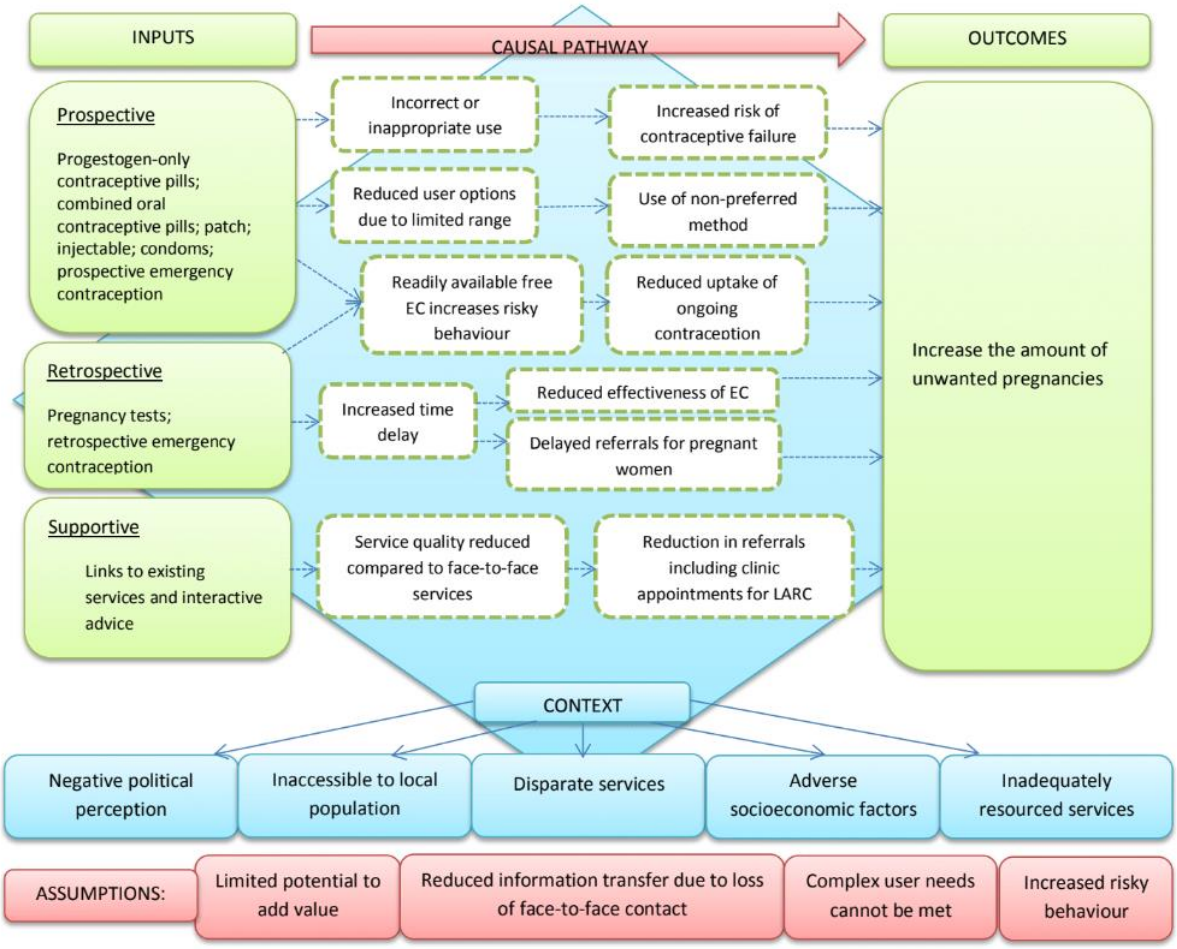


Figure 2 Theory of change diagram based on the SH:24 funding application and original stakeholder interview. Presents only the negative causal pathways leading to detrimental public health outcomes

Appendix L. CiP-CO Study Participant Information Sheet

King's College Hospital NHS Foundation Trust

KING'S College LONDON

Participant Information Sheet

Contraception continuation, knowledge and service use among new oral contraceptive pill (OCP) users of face-to-face and internet-based services: a cohort study - The Contraception in Person – Contraception Online (CiP-CO) Study

We are inviting you to take part in a research study. Before you decide, it is important that you know why we are doing the study and what is involved. Please read the following information carefully.

What is the study?

This study is looking at how women access and experience the different contraception services that are freely available to people who live in Lambeth or Southwark. It will examine the access of repeat supplies of contraception, contraceptive knowledge and contraceptive service-use among women who have come to a service to access a 3 month supply of pills.

Why have I been chosen?

You have been chosen as you live in the borough of Lambeth or Southwark, you are over 16 and you are a new user of oral contraceptive pills accessing a 3 month supply during the study period.

Do I have to take part?

No, it is up to you to decide whether you would like to take part.

What will happen if I take part?

After you have had all your questions answered and have agreed to take part, we will ask you to provide consent and your name, address and other contact information. You can do this on our secure and confidential study website. Within the next 6 days we will send you the first questionnaire, which will ask you what service you used to access your most recent supply of contraception, your recent reproductive and contraceptive history and your motivation around using contraception at this time. We will also ask you some basic questions about what you know about safe and effective use of contraception. We will confirm your attendance for your most recent supply of contraception by checking your records at this service.

In approximately 4 months we will contact you again to complete another short questionnaire. This time we will ask you a bit about your experiences with your 3 month pill supply and what you did about your contraception once this supply ran out. You can complete this questionnaire online or by phone or post if you prefer.

We will also ask your contraceptive health service to provide the research team details of any visits for information, advice or supplies of contraception undertaken during your involvement in the study.

What are the alternatives?

You do not have to take part.

What are the possible disadvantages in taking part?

Completing the first questionnaire within the first 6 days will take up around 10 minutes of your time. The second questionnaire in 4 months will also take up around 10 minutes of your time.

It is possible that if you do this whilst around other people, they may see you using the study website or filling in the questionnaires about your experiences relating to contraception. If you are worried about this, you can access the study website in a private place (such as your bedroom) and from a hand held device such as a smart phone or tablet. You also do not have to answer any questions that you do not want to.

What are the possible benefits of taking part?

Taking part in this study will help us find out more about how women access and experience different contraception services. It will help us learn how to maximise women's contraceptive choices and abilities to access contraception effectively.

This is particularly important now because contraception services are undergoing changes, e.g. women can now access their free, NHS contraception via the internet-based service, SH:24.

Will you compensate me for the time this takes?

You will receive £5 for completing the first questionnaire within 6 days. This will be sent once we have confirmed your attendance at the service you tell us you got your recent supply of contraceptive pills from.

You will receive a further £10 once we have received your follow up questionnaire at 4 months.

What happens when this study stops?

When the study stops, we will describe how many people are still using contraception, how long it took them to get new supplies, where they went to get it and their level of contraceptive knowledge and compare these outcomes according to which type of service women first accessed for their 3 month pill supply.

What will happen if I don't want to carry on with the study?

You can withdraw at any time by letting the Study Coordinator know (contact details below). You do not have to give a reason for wanting to withdraw.

What if there is a problem?

You can contact the Study Coordinator if there is a problem. If you would like to make a formal complaint, contact Dr Paula Baraitser who will follow the complaints procedure.

Will my taking part in this study be kept confidential?

Yes. All information about your use of contraceptive services and your responses to the questionnaires will be coded so it is anonymous and kept in a separate database from your identifiable information at all times. Personal details will be stored on a password protected computer at a secure site and only researchers responsible for contacting participants will have access to this. Your information will be deleted at the end of the study as per King's College Hospital (KCH) Trust policy.

We will not inform any of your family or friends or your GP about your involvement in this research.

We will only contact your GP if you have told us that this is where you have accessed your contraception.

What will happen to the results of the research study?

The results will be published in a scientific journal so that other people know about it.
None of the participants will be identifiable from the published data. If you would like a copy of the results please contact the Study Coordinator.

A lay summary of the research results will be placed on the King's College London website.

Who is organising and funding the research?

The study is run by Dr Paula Baraitser (Chief Investigator) from King's College London and is part of a PhD and a large evaluation of online services. The research is being funded by Guy's and St Thomas' charity (http://www.gsttcharity.org.uk/).
The study has been fully reviewed and given a favourable opinion by the London - Dulwich Research Ethics Committee.

King's College London no harm statement:

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [see contact details below].
In the event that something does go wrong and you are harmed during the research then you may have grounds for legal action for compensation against King's College London but you may have to pay your legal costs. King's College London maintains adequate insurance to cover any liabilities arising from the study.

Thank you for taking the time to consider taking part.
If you would like further information please contact Emma Rezel
The team contact details:

Emma Rezel (Study Coordinator)
Global Health
King's College London
Cutcombe Street
London
SE5 9RJ
Email: emma.rezel@kcl.ac.uk
Tel: 0207 848 5052

Dr Paula Baraitser (Chief Investigator)
Weston Education Centre
King's College London
10 Cutcombe Road
London
SE5 9RJ
Email: paula_baraitser@mac.com Tel: 07525 630865

Should you have concerns about your NHS care please contact Patient Advice and Liaison Services (PALS).

The following contact details are for PALS at King's College Hospital NHS Foundation Trust
PALS at King's College Hospital NHS Foundation Trust
Denmark Hill
London
SE5 9RS
Email: kch-tr.PALS@nhs.net
Tel: 020 3299 360

Appendix M. CiP-CO Study Consent Form

Study Number:

Patient Identification Number for this trial:

CONSENT FORM

Title of Project: Contraception continuation, knowledge and service use among new oral contraceptive pill (OCP) users of face-to-face and internet-based services: a cohort study -

The Contraception in Person – Contraception Online (CiP-CO) Study

Principal Investigator: Dr Paula Baraitser
Please read the following statements carefully and tick all boxes

I confirm that I have read and understand the information sheet [version X, 2016] for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

I understand that my participation is voluntary (my choice) and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

I understand that all information I provide will remain confidential in accordance with the Data Protection Act of 1998 and will only be used for the purposes of the study. Only the research team directly involved with the study will have access to this information. ☐

I understand that relevant sections of data collected during the study, may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

I agree to the research team accessing records from the service that I report having used for contraception to confirm details of attendance for my latest supply of contraceptive pills during the time that I am involved in the study. ☐

In the event that I report getting contraception from a named General Practice (GP), I agree to the research team confirming this by contacting this service and accessing the relevant records. ☐

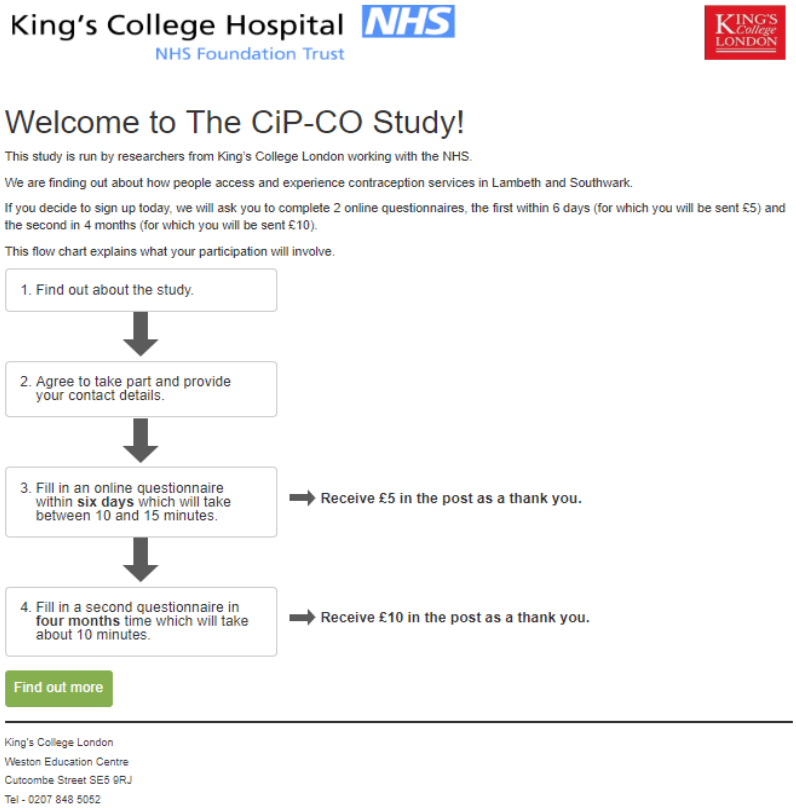
I agree to take part in the above study. ☐

Name of participant	Signature	Date
Name of person taking consent	Signature	Date

If you need more information to help you decide, please contact:

Emma Rezel (Study Coordinator)
King's College London
Cutcombe Street
London
SE5 9RJ
Email: emma.rezel@kcl.ac.uk **Tel:** 0207 848 5052

Appendix N. CiP-CO Study Website



King's College Hospital NHS
NHS Foundation Trust

Welcome to The CiP-CO Study!

This study is run by researchers from King's College London working with the NHS.

We are finding out about how people access and experience contraception services in Lambeth and Southwark.

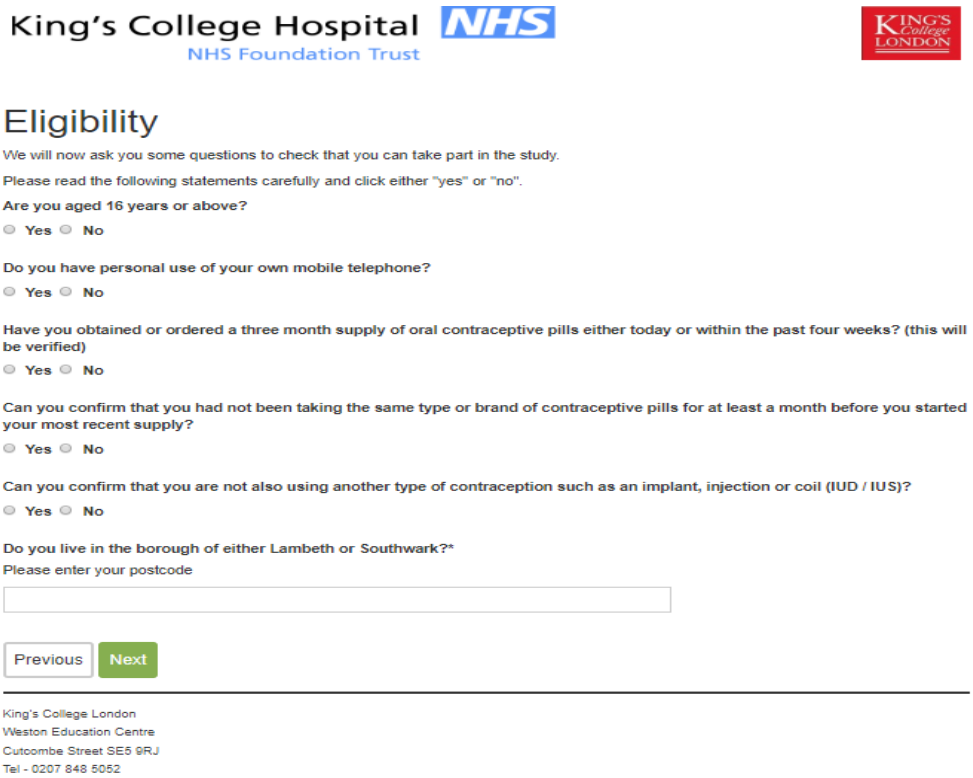
If you decide to sign up today, we will ask you to complete 2 online questionnaires, the first within 6 days (for which you will be sent £5) and the second in 4 months (for which you will be sent £10).

This flow chart explains what your participation will involve.

1. Find out about the study.
2. Agree to take part and provide your contact details.
3. Fill in an online questionnaire within **six days** which will take between 10 and 15 minutes. → Receive £5 in the post as a thank you.
4. Fill in a second questionnaire in **four months** time which will take about 10 minutes. → Receive £10 in the post as a thank you.

Find out more

King's College London
Weston Education Centre
Cutcombe Street SE5 9RJ
Tel - 0207 848 5052



King's College Hospital NHS
NHS Foundation Trust

Eligibility

We will now ask you some questions to check that you can take part in the study.

Please read the following statements carefully and click either "yes" or "no".

Are you aged 16 years or above?

○ Yes ○ No

Do you have personal use of your own mobile telephone?

○ Yes ○ No

Have you obtained or ordered a three month supply of oral contraceptive pills either today or within the past four weeks? (this will be verified)

○ Yes ○ No

Can you confirm that you had not been taking the same type or brand of contraceptive pills for at least a month before you started your most recent supply?

○ Yes ○ No

Can you confirm that you are not also using another type of contraception such as an implant, injection or coil (IUD / IUS)?

○ Yes ○ No

Do you live in the borough of either Lambeth or Southwark?*

Please enter your postcode

Previous Next

King's College London
Weston Education Centre
Cutcombe Street SE5 9RJ
Tel - 0207 848 5052

Appendix O. CiP-CO Study Promotional Text Messages

Hello. King's College London are running a study about local contraception services. If you take part and complete our online questionnaires, you will be sent £15 to thank you for your time. Follow this link www.cipco.org.uk to find out more or text back YES to receive a call from a member of our research team. Please ignore this if you have already signed up.

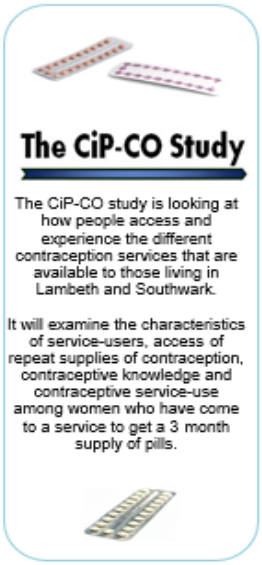
Hello. King's College London are running a study on contraception. You get £15 for doing 2 questionnaires. Sign up at www.cipco.org.uk. Thanks. SH:24

Hello. King's College London are running a study on contraception. You get £15 for doing 2 questionnaires. Over 400 people have signed up, you can too at www.cipco.org.uk. Thanks. SH:24

Participating in King's College London's study on contraception will help researchers understand how to improve local services. Don't miss out, sign up at www.cipco.org.uk. Thanks. SH:24

Hello. King's College London are running a study on contraception. You get £15 for doing 2 questionnaires. These are your final few days to sign up at www.cipco.org.uk. Thanks.

Appendix P. CiP-CO Study Promotional Leaflet



The CiP-CO Study

The CiP-CO study is looking at how people access and experience the different contraception services that are available to those living in Lambeth and Southwark.

It will examine the characteristics of service-users, access of repeat supplies of contraception, contraceptive knowledge and contraceptive service-use among women who have come to a service to get a 3 month supply of pills.

The CiP-CO Study

The Contraception Online - Contraception in Person Study

What is it about?

King's College Hospital NHS

The CiP-CO Study — **King's College London**

Weston Education Centre
Cutcombe Road
London SE5 9RJ
Emma.rezel@kcl.ac.uk

Tel: 0207 848 5052

The CiP-CO Study

- **Have you just accessed a three-month supply of oral contraceptive pills?** ✓
- **Do you live in Lambeth or in Southwark?** ✓
- **Are you willing to be part of our research and receive £15?** ✓

Complete this form and leave it with your contraception provider. A King's College London researcher will contact you within the next few days to invite you to the study.

Tick the box to indicate that you consent to being contacted by a King's College London Researcher. ☐

Today's Date: _____

Name: _____

Mobile No.: _____

We will ask you to complete a short, online questionnaire about contraception within **6 days** after you sign up and again in **4 months** when we will ask you a bit about your experiences with your 3 month pill supply and what you did about your contraception once this supply ran out.

We will give you £15 cash to compensate you for your time.

By taking part in this study you will help us find out which contraceptive services work best and contribute to the improvement of how contraceptive services are delivered in Lambeth and Southwark

Appendix Q. CiP-CO Study Promotional Cards and Pill Labels

Side One

Side Two

Side Two (Alternative)

Pill Label


KING'S College LONDON
Do you live in Lambeth or Southwark?
Have you recently got a 3 months' supply of the contraceptive pill?
Get £15 cash for doing 2 online questionnaires about contraception, sign up at:
www.cipco.org.uk

Appendix R. CiP-CO Study Letter Template for GP follow-up

Weston Education Centre,
King's College London,
Cutcombe Road,
London
SE5 9RJ

11 July 2019

Dear [Name],

The sexual health research group at King's College London has recently conducted a study with the NHS to evaluate contraceptive services in Lambeth and Southwark. The aim of the study is to improve access to contraceptive services for women living in these boroughs. It has been funded by Guys and St. Thomas' Charity and ethical approval has been granted by the London - Dulwich Research Ethics Committee.

[number] of our study participants reported that they used [name of surgery] to get their contraception during the study. This/these participant/s has/have given permission for us to contact you to verify this.

I would be very grateful if you could verify this by checking their service records and replying to this email with the following information:

1. Did [NAME], DOB [DOB], attend your service since [Date 1]?
2. Did they attend to receive a **contraceptive method** and/or **contraceptive advice** during this period?

3. If Yes, please tell us about 1) the type and quantity of each contraceptive method received and 2) details of the contraceptive advice given at each attendance:

Date of Attendance	Type and Quantity of Contraceptive Method Received *(e.g. 3 months supply of combined pill)*	Details of Contraceptive Advice, e.g. concerns about missed pills or unprotected sexual intercourse (UPSI)

I've enclosed notices of favourable ethical opinion, copies of participants' informed consent form (given online via the study website) and the participant information sheet. The consent was taken online so I have attached screen shots of the consent questions and our electronic record of the participant's responses to those questions.

If you have any questions, please do not hesitate to contact me on 07793053912

Thank you very much for your assistance in this matter.

Yours faithfully,

Emma Rezel (Study Coordinator)

On behalf of Dr. Paula Baraitser (Chief Investigator),
GUM Consultant, Kings College Hospital.

Appendix S. Free text responses to CiP-CO Study, Questionnaire 2 statement, “Please provide any additional comments about the CiP-CO study”

Free text responses were thematically analysed using an inductive approach to code data according to the themes grounded in the data.

Service Rating: Free Text Responses

A total of 30 participants provided data in the form of a free text response regarding the CiP-CO Study.

1. General comments

Participants provided some general, non-specific comments which indicated an overall positive experience of the research.

> “Easy to complete and no hassle.”
>
> “Good study”
>
> “useful and hope it helps the study”

Some participants appeared to not have a clear understanding that the research team was a separate entity to their contraceptive provider. This may be due to the recruitment taking place within the physical services and, for those recruited via SH:24, using the same text-based communication platforms.

> “All was ok. Service was fine.”

2. Knowledge

Several comments concerned a positive reaction to the knowledge questions explored in Chapter 7. Respondents appeared to appreciate being tested on their knowledge of OCPs and liked that it highlighted areas they should be aware of for safe and effective use of contraception.

> “Helped refresh my knowledge of the pill and encouraged me to look into the leaflet further.”
>
> “The study has given me more insight about the use of contraception pill, and how to correctly take the pills”
>
> “Gain information about sexual health which is very useful”

3. The purpose of the study

There were some comments which suggested the participants had considered what the potential purpose of the study could be, although these did not correspond to the aims of the study as stated in the participant information sheet (Appendix L).

> “Good to find out what women think of different contraceptions.”

"I think it will help women decide what contraception is for them."

Another participant suggested a pertinent topic for further research.

"I think it would be great to also research the effect of the pill on women's mental and physical health, as well as the accessibility of the pill."

4. Study Quality

Some participants chose to comment on the overall study quality in terms of design and ease of participation.

"Extremely easy to access and complete"

"The questions were very clear and concise."

"Very well structured"

Conclusions

This descriptive analysis of the free text comments on the CiP-CO study indicate that those participants who opted to respond to this section of the questionnaire had an overall positive experience of participation. It also indicates that an unintended consequence of this study has been to encourage some respondents to think more carefully about the information they should know about safe and effective use of the pill. The implications for future contraceptive research are:

1. The wording, structure and delivery of the online questionnaires appears to have been positively received by participants.

2. New OCP-users may benefit from testing their contraceptive knowledge through a questionnaire delivered in this way.

3. Despite efforts to convey the aims and objectives of the study and information about the research group conducting the study, some participants had misinformation about these aspects. Further research in this area may benefit from pilot testing of the participant information sheet and other information-giving elements of the study design to ensure that participants have a clear understanding of these elements of the study.

4. Very few participants responded to the request for further comment. A better response rate may have been achieved through making this a mandatory element of the questionnaire.

Appendix T. Letters of ethical approval

NRES Committees - North of Scotland
Summerfield House
2 Eday Road
Aberdeen
AB15 6RE

Telephone: 01224 558458
Facsimile: 01224 558609
Email: nosres@nhs.net

NHS Grampian

8 April 2015

Dr Paula Baraitser
Consultant in Sexual Health Medicine
King's College Hospital
Camberwell Building
94-104 Denmark Hill
LONDON
SE5 9RS

Dear Dr Baraitser

Study title:	**Economic and epidemiological evaluation of SH:24, a redesigned complete sexual health service**
REC reference:	**15/NS/0031**
IRAS project ID:	**169251**

The Proportionate Review Sub-Committee of the NRES Committees - North of Scotland (1) reviewed the above application by correspondence.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Mrs Carol Irvine, nosres@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

On behalf of the Committee, the Proportionate Review Sub-Committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
IRAS Checklist XML: Checklist 24032015		24 March 2015
Peer Review		28 October 2014
REC Application Form: REC Form 24032015		24 March 2015
Research protocol or project proposal	1	23 January 2015
Summary CV for Chief Investigator (CI): Paula Baraitser		22 July 2014

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

15/NS/0031	**Please quote this number on all correspondence**

Yours sincerely

Professor Helen Galley
Chair

Enclosures: List of names and professions of members who took part in the review
"After ethical review – guidance for researchers" SL-AR2

Copy to: The Research Office, King's College Hospital NHS Foundation Trust

NHS
Health Research Authority

Dr Paula Baraitser
Senior Lecturer
Kings College Hospital NHS Foundation Trust/ Kings College London
Weston Education Centre
Denmark Hill
London
SE5 9RJ

Email: hra.approval@nhs.net

15 September 2016

Dear Dr Baraitser

Letter of HRA Approval

Study title:	**Contraception Continuation, Knowledge and Service Use Among New Oral Contraceptive Pill Users of Face-to-Face and Internet-Based Services: A Cohort Study**
IRAS project ID:	**203076**
REC reference:	**16/LO/1025**
Sponsor	**King's College London**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators"*, issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

IRAS project ID	203076

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at hra.approval@nhs.net. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **203076**. Please quote this on all correspondence.

Yours sincerely

Alison Thorpe
Senior Assessor

Email: hra.approval@nhs.net

Copy to: *Mr Keith Brennan, King's College London, Sponsor Contact*
Ms Liba Stones, King's College Hospital NHS Foundation Trust, Lead NHS R&D Contact

NHS
Health Research Authority

London - Dulwich Research Ethics Committee

Health Research Authority
Skipton House
80 London Road
London
SE1 6LH

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

08 March 2017

Dr Paula Baraitser
Senior Lecturer
Kings College Hospital NHS Foundation Trust/ Kings College London
Weston Education Centre
Denmark Hill
London
SE5 9RJ

Dear Dr Baraitser

Study title:	**Contraception Continuation, Knowledge and Service Use Among New Oral Contraceptive Pill Users of Face-to-Face and Internet-Based Services: A Cohort Study**
REC reference:	**16/LO/1025**
Amendment number:	**1**
Amendment date:	**09 February 2017**
IRAS project ID:	**203076**

The above amendment was reviewed at the meeting of the Sub-Committee held in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Notice of Substantial Amendment (non-CTIMP)	1	09 February 2017

Other [Invitation OCP continuation Study Face to Face Version 3 06_05]	3	06 May 2016
Other [Invitation OCP continuation Study Face to Face 04_11_16_Version 7]	7	04 November 2016
Other [Advertising Card for Potential participants CiPCO Study Version 1 12_01_17]	1	12 January 2017
Other [Advertising Pill Label for Potential participants CiPCO Study Version 1 12_01_17]	1	12 January 2017
Other [Invitation OCP continuation Study Face to Face 12_01_17_Version 8]	8	12 January 2017
Other [Poster Advertisement for potential participants OCP continuation Version 2 12_01_17]	2	12 January 2017
Research protocol or project proposal [Contraception Continuation Protocol V9 12_01_17]	9	12 January 2017

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

16/LO/1025: Please quote this number on all correspondence

Yours sincerely

PP
Dr Michael Philpot
Chair

E-mail: nrescommittee.london-dulwich@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Mrs Liba Stones, King's College Hospital NHS Foundation Trust*
Mr Keith Brennan

Paula Baraitser
Global Health Unit
Room 2.08, Weston Education Centre
Cutcombe Road
SE5 9RJ

12 March 2014

Dear Paula Baraitser

BDM/13/14-42 Understanding how and why online sexual health services might be an effective alternative to clinic based care.

Review Outcome: Full Approval

Thank you for sending in the amendments/clarifications requested to the above project. I am pleased to inform you that these meet the requirements of the BDM and therefore that full approval is now granted.

Please ensure that you follow all relevant guidance as laid out in the King's College London Guidelines on Good Practice in Academic Research (http://www.kcl.ac.uk/college/policyzone/index.php?id=247).

For your information ethical approval is granted until **12th March 2015**. If you need approval beyond this point you will need to apply for an extension to approval at least two weeks prior to this explaining why the extension is needed, (please note however that a full re-application will not be necessary unless the protocol has changed). You should also note that if your approval is for one year, you will not be sent a reminder when it is due to lapse.

Ethical approval is required to cover the duration of the research study, up to the conclusion of the research. The conclusion of the research is defined as the final date or event detailed in the study description section of your approved application form (usually the end of data collection when all work with human participants will have been completed), not the completion of data analysis or publication of the results. For projects that only involve the further analysis of pre-existing data, approval must cover any period during which the researcher will be accessing or evaluating individual sensitive and/or un-anonymised records. Note that after the point at which ethical approval for your study is no longer required due to the study being complete (as per the above definitions), you will still need to ensure all research data/records management and storage procedures agreed to as part of your application are adhered to and carried out accordingly.

If you do not start the project within three months of this letter please contact the Research Ethics Office.

Should you wish to make a modification to the project or request an extension to approval you will need approval for this and should follow the guidance relating to modifying approved applications:
http://www.kcl.ac.uk/innovation/research/support/ethics/applications/modifications.aspx
The circumstances where modification requests are required include the addition/removal of participant groups, additions/removal/changes to research methods, asking for additional data from participants,

extensions to the ethical approval period. Any proposed modifications should only be carried out once full approval for the modification request has been granted.

Any unforeseen ethical problems arising during the course of the project should be reported to the approving committee/panel. In the event of an untoward event or an adverse reaction a full report must be made to the Chair of the approving committee/review panel within one week of the incident.

Please would you also note that we may, for the purposes of audit, contact you from time to time to ascertain the status of your research.

If you have any query about any aspect of this ethical approval, please contact your panel/committee administrator in the first instance (http://www.kcl.ac.uk/innovation/research/support/ethics/contact.aspx). We wish you every success with this work.

With best wishes

Yours sincerely

Annah Whyton – Research Support Assistant