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Facilitators and barriers to chlamydia testing in general practice for young people using a theoretical model (COM-B): A systematic review protocol

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3 **FACILITATORS AND BARRIERS TO CHLAMYDIA TESTING IN GENERAL**
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5 **PRACTICE FOR YOUNG PEOPLE USING A THEORETICAL MODEL (COM-B):**
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7 **A SYSTEMATIC REVIEW PROTOCOL**
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ABSTRACT

Introduction

Chlamydia is a key health concern, with high economic and social costs. There were over 200,000 chlamydia diagnoses made in England in 2015. The burden of chlamydia is greatest among young people where the highest prevalence rates are found. Annual testing for sexually active young people is recommended in England; however, many of those at risk do not receive testing. General practice has been identified as an ideal setting for testing, yet previous research to increase testing in this setting has not been effective. One theoretical model which may provide insight into the underpinnings of chlamydia testing behaviour is the Capability, Opportunity, and Motivation Model of Behaviour (COM-B Model). The aim of this systematic review is to: (1) identify the barriers and facilitators to chlamydia testing for young people in general practice, and (2) use a theoretical model, the COM-B Model, to conduct a behavioural analysis of chlamydia testing behaviour.

Methods and analysis

Qualitative, quantitative, and mixed methods studies published after 2000 will be included. Seven databases (MEDLINE, PubMed, Embase, Informit, PsycInfo, Scopus, and Web of Science) will be searched to identify peer-reviewed publications which examined barriers and facilitators to chlamydia testing in general practice. Risk of bias will be assessed using criteria based Critical Appraisal Skills Programme. Data regarding study design and key findings will be extracted. The data will be analysed using thematic analysis and the resultant factors will be mapped onto the components of the COM-B Model. All findings will be reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.

Ethics and dissemination

Ethical approval is not required. The review findings will be used to inform the development of interventions to facilitate effective and efficient chlamydia testing in general practice.

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For peer review only

INTRODUCTION

Chlamydia is a key public health concern, with great economic and social costs. There were 200,288 chlamydia diagnoses made in England in 2015,[1]. The burden of chlamydia is greatest among people aged 15-24 years where the highest prevalence rates are found,[1].

Chlamydia is often asymptomatic and can pose severe health consequences if left undiagnosed and/or untreated (i.e., pelvic inflammatory disease, infertility, ectopic pregnancy). Testing and early treatment, therefore, is an effective way to interrupt the transmission chain in the population and prevent such sequelae,[2].

Chlamydia testing in general practice

General practice is a logical setting for chlamydia testing for a variety of reasons. Over 60% of young people attend general practice annually,[3, 4]. Young people have reported a preference to receive testing and testing results from a general practitioner,[5-8]. Higher rates of positivity have been found, particularly for males, in general practice compared to non-healthcare settings such as universities,[9, 10]. Finally, regular screening is easier to maintain in this setting, due to patients attending for other reasons which is necessary for continued transmission reduction,[9].

Barriers and facilitators to chlamydia testing

Annual testing for sexually active young people is recommended in several countries including Australia, Denmark, England, Norway, Sweden, and the USA,[11-15].

Unfortunately, however, many of those at risk do not receive testing. Despite the central role of primary care in chlamydia control, only 19% of chlamydia tests were performed in general practice in England in 2015,[1].

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3 Lack of testing has been attributed to barriers at the patient level, provider level, and
4 system level. In a recent narrative review of chlamydia testing in general practice, the most
5 common barriers identified were the social context of testing (i.e., stigma), poor
6 knowledge/training, and time constraints,[16]. However, the review was conducted using a
7 narrative approach, and thus lacks the rigorous methodological techniques of the systematic
8 review. It is possible that potentially relevant studies were missed.
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11 To overcome the barriers to testing and explore the facilitators, numerous
12 interventions using a variety of strategies have been conducted,[17, 18]. The evidence for
13 their effectiveness is mixed. For those that have been reported as being effective, the effects
14 tend to be modest,[19, 20] or demonstrate little clinical significance,[21]. One possible
15 explanation for these disappointing results is the lack of input from theories of behaviour and
16 behaviour change.
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32 **The role of theory**

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34 It is increasingly recognised that an understanding of behaviour and behaviour change is
35 required to maximise the effectiveness of interventions,[22]. Essentially, in order to change a
36 particular behaviour (such as increase chlamydia testing), it is necessary to have a theoretical
37 understanding of that behaviour,[23, 24]. Applying theory to intervention design allows
38 researchers to explain and predict specific behaviours in terms of why, when, and how they
39 occur, as well as which factors should be targeted to in order to alter them.
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47 The few published studies on chlamydia testing that have taken a theoretical approach
48 have repeatedly used the same theory or used inappropriate theories. This means that other
49 important factors can be excluded,[25]. For example, the Theory of Planned Behaviour
50 (TPB,[26, 27]) proposes that one's intentions (e.g., intention to offer an chlamydia test) are
51 influential in bringing about behaviour change (e.g., offering an chlamydia test). According
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3 to the TPB, intentions are the result of a combination of three factors: personal attitude (e.g.,
4 one's belief in the benefits of testing), subjective norms (e.g., whether one feels social
5 pressure to offer a test) and perceived behavioural control (e.g., one's confidence in their
6 ability to test),[28-30]. This, however, omits other significant influences on chlamydia
7 testing, such as one's sexual history, self-identity, and previous chlamydia testing
8 experience,[28, 31, 32]. Moreover, although intentions have been found to be important in
9 predicting behaviour, a direct link does not always exist between two,[33-36]. To increase an
10 individual's probability of being tested, it is not sufficient to strengthen one's intentions:
11 intentions need to be acted upon,[37].

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14 A promising solution to the problems associated with this approach, is to conduct a
15 behavioural analysis of the issue (i.e., chlamydia testing behaviour) using a theoretical model
16 of behaviour change. The COM-B Model (capability, opportunity, motivation, behaviour)
17 proposes that behaviour (B) is the result of an interaction between three components;
18 capability (C), opportunity (O) and motivation (M). Behaviour change, therefore, requires a
19 change in one or more of these components. The COM-B Model lies at the centre of the
20 Behaviour Change Wheel (a tool kit for designing behaviour change interventions,[38]) and
21 is the starting point of intervention development. Capability can be psychological or physical;
22 opportunity can be social or physical; motivation can be automatic or reflective. In other
23 words, for a person to engage in a specific behaviour, they need to: (1) be psychologically
24 and physically able to do the behaviour; (2) have the physical and social opportunity to do the
25 behaviour; and (3) want or need to do the behaviour. The model is illustrated in Figure 1. The
26 benefit of employing the COM-B Model over a single theory of behaviour change is that
27 several distinct explanatory components are outlined; thus, additional potential influences on
28 behaviour can be considered which is essential for the development of an intervention.
29 Furthermore, once the COM-B Model has been used to conduct an in-depth theoretically-

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3 based analysis of the behaviour in question, it can be ultimately used to identify the mediators
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5 and moderators of behaviour to be targeted by an intervention,[39].
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9 10 **Research aims**

11 The aim of this systematic review is to identify the barriers and facilitators to chlamydia
12 testing for young people in general practice and to use the COM-B Model to conduct a
13 behavioural analysis of chlamydia testing. The specific research questions of this systematic
14 review are:
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- 20 1. What are the facilitators and barriers to chlamydia testing for young people in general
21 practice?
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- 23 2. What are the facilitators and barriers to chlamydia testing for healthcare professionals
24 in general practice?
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- 26 3. How do identified facilitators and barriers of chlamydia testing for young people in
27 general practice map on to a theoretical model of behaviour change?
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- 29 4. How do identified facilitators and barriers of chlamydia testing for healthcare
30 professionals in general practice map on to a theoretical model of behaviour change?
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40 **METHODS AND ANALYSIS**

41 This systematic review will be conducted in accordance with the Preferred Reporting Items
42 for Systematic Reviews and Meta-Analyses (PRISMA) Statement guidelines,[40]. The
43 PRISMA-Protocol checklist is presented in Appendix 1. This review is registered with the
44 international database of prospectively registered systematic reviews in health and social care
45 (PROSPERO; registration number CRD42016041786; available at
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60 http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42016041786).

Eligibility criteria

To be included in the review, papers will have to meet the following PICOS (Population, Intervention, Context, Outcomes and Study design) elements:

1. Population

Inclusion criteria:

- Young men and women (aged 15-24 years) and healthcare providers (general practitioners, practice nurses, nurse practitioners).

Exclusion criteria:

- Studies focusing exclusively on commercial sex workers, incarcerated people, people living with HIV, victims of sexual or domestic abuse or violence, intravenous drug users, and individuals with no fixed address as these groups have distinct needs beyond the scope of the review.

2. Intervention

The issue to be reviewed is opportunistic and systematic chlamydia testing for young people in general practice. Opportunistic testing will be defined as the offer of a diagnostic test to people attending general practice during a consultation for another reason. Systematic testing will be defined by the use of existing population registers to invite the target group to submit self-collected samples by post. A barrier will be defined as a factor that obstructs or prevents chlamydia testing; a facilitator will be defined as a factor that supports or promotes chlamydia testing.

Inclusion criteria:

- Randomized and non-randomized controlled trials, pre- and post-test designs, non-experiment observational (cross-sectional, case-series, case studies), and qualitative papers (interviews, focus groups).

Exclusion criteria:

- Exclusively set outside of general practice, exclusively focused on partner notification, campaigns exclusively focused on health promotion, and testing for diagnostic purposes when symptoms are present.

3. Context

Inclusion criteria:

- Studies conducted in Australia, Denmark, Ireland, Netherlands, New Zealand, and the UK as the model of delivering healthcare in general practice is comparable.

Exclusion criteria:

- Studies conducted in low income countries as the general practice setting is not comparable.

4. Outcomes

Primary outcomes

- Young people: Perceived facilitators to chlamydia testing, perceived barriers to chlamydia testing, views towards chlamydia testing, and acceptability of chlamydia testing.
- Healthcare providers: Perceived facilitators to chlamydia testing, perceived barriers to chlamydia testing, views towards chlamydia testing, and acceptability of chlamydia testing.

Secondary outcomes

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3 Classification of the identified barriers and facilitators into the sub-components of the COM-
4 B Model: psychological capability, physical capability, social opportunity, physical
5 opportunity, automatic motivation, and reflective motivation.
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10 11 12 5. Study design

13 *Inclusion criteria:*

- 14 – Quantitative (i.e., cross-sectional, case-series, and case studies), qualitative, and
15 mixed method studies.
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20 *Exclusion criteria:*

- 21 – Commentary or opinion publications that do not present new data.
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28 **Information sources**

29 The review will access both published and unpublished material by searching literature
30 sources listed below between January 2000 and March 2016. Pre-2000 studies will be
31 excluded as Nucleic Acid Amplification Tests (NAATs) of urine samples were introduced
32 around this time, thus widening testing to non-clinical settings. The following databases will
33 be searched: MEDLINE, Pubmed, Embase, Informit, Web of Science, PsycINFO, and
34 Scopus. Relevant articles will also be identified from a hand search of reference lists of
35 included articles.
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47 **Search strategy**

48 Medical Subject Headings (MeSH), subject headings and keywords will be created by using
49 language that describes facilitators and barriers to chlamydia testing in general practice.
50 Boolean combinations will create more specific searches. The search strategy presented in
51 Appendix 2 will be used to search MEDLINE, using an Ovid platform. Search terms will be
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3 modified for other databases where subject heading indexing differ from the terms used in
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5 MEDLINE.
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9 10 **Data extraction and management**

11 Data will be extracted from all full text studies that fulfil the inclusion criteria. The reviewers
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13 will characterise the research design used in each study, including study population, sample
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15 size, response rate (if described), randomization (if RCT), presence or absence of a
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17 comparison group, data collection methods, and key findings (primary/secondary outcomes).
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20 A standardised framework will be devised and used to record the aims,
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22 methodological characteristics, main findings and relevance of each study. All identified
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24 references will be stored in Endnote. Data extraction will be undertaken by one reviewer
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26 (LMD) and checked by a second reviewer (HB/TH). Any discrepancies will be resolved by
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28 discussion between two researchers or adjudication by a third reviewer (GR/JC) when
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30 necessary. If required, primary authors will be contacted for additional data.
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36 All studies that meet the inclusion criteria will be described in terms of:

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38 – Design and quality, data collection methods, modes and techniques; validity of tools;
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40 qualitative, statistical and other analyses
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42 – Participants, demographic characteristics (e.g., age, ethnicity)
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44 – Setting and recruitment methods, details of modes of delivery and any other aspects of
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46 content
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48 – Theoretical framework employed in study (if any)
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54 The following data will be extracted:

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56 1. Data relating to young people:
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3 – Perceived facilitators to chlamydia testing, perceived barriers to chlamydia
4 testing, reasons for accepting or refusing the offer of chlamydia testing, and
5 acceptability of chlamydia testing in general practice.
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10 2. Data relating to healthcare providers:

- 11 – Perceived facilitators to chlamydia testing, perceived barriers to chlamydia
12 testing, provider reasons for providing chlamydia testing to young people, and
13 acceptability of chlamydia testing in general practice.
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21 **Risk of bias (quality) assessment**

22 The quality of each paper will be assessed independently by two reviewers (LMD and
23 HB/TH). Any discrepancies will be resolved by consensus and, if necessary, a third party will
24 be consulted. Each paper will be assessed using criteria based on the Critical Appraisal Skills
25 Programme,[41]. Individual studies will be classified as primary (high quality studies
26 providing theoretical insight into sexual behaviour or thorough descriptions of particular
27 contexts) and secondary (lower quality studies that had simple, non-detailed descriptions or
28 do not support statements with evidence). The critical appraisal process will not be used to
29 exclude papers prior to the synthesis; rather, it will be used to provide a context for the
30 interpretation of the synthesised findings.
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45 **Data synthesis and analysis**

46 Individual study characteristics and outcomes will be summarised and presented in an
47 evidence table. Thematic analysis, employing expert guidelines,[42] will be used to identify
48 prominent/recurrent themes in the literature. The use of the statistical software package
49 NVivo11 will aid in managing the coding of the data set, with each code (or node)
50 representing the emergent themes, e.g., “education”. The frequency of themes as well as their
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3 explanatory value will be assessed. The themes will be refined through discussion and the use
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5 of constant comparison within and between codes to ensure that they accurately reflect the
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7 material.
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10 Finally, a behavioural analysis of chlamydia testing behaviour will be conducted.
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12 Specifically, the identified themes will be classified into the six sub-components of the COM-
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14 B Model (psychological capability, physical capability, social opportunity, physical
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16 opportunity, automatic motivation, and reflective motivation; see Figure 1). Data
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18 classification will be conducted by one reviewer (LMD) in consultation with members of the
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20 review team (JS, JC, HB, TH, and GR), employing guidelines set out by Michie and
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22 colleagues,[38]. Any discrepancies will be resolved by consensus.
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27 **DISCUSSION AND DISSEMINATION**

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29 To the authors' knowledge, this is the first systematic review to conduct a theoretical
30
31 behavioural analysis of barriers and facilitators to chlamydia testing for young people in
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33 general practice. A theoretically-based framework will be generated which will provide a
34
35 greater insight into the complexities of chlamydia testing. The findings will have relevance to
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37 healthcare professionals, policy-makers and commissioners in informing how best to improve
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39 the sexual health of young people. Importantly, the results will be integral to inform the
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41 development of interventions that will facilitate effective and efficient access to care and
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43 treatment for chlamydia in primary care, with the aim of reducing morbidity and transmission
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45 of chlamydia.
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50 The review results will be disseminated via submission for publication to a peer-
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52 review journal when complete and submissions to be presented at national and international
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54 conferences (where eligible). Furthermore, lay and scientific summaries will be produced for
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56 wider dissemination (e.g., via newsletters, blogs, and organisation meetings).
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Authors' contributions:

GR and JC designed the study and obtained funding. LMD developed and refined the study protocol with contributions from all co-authors (JS, JC, HB, TH, and GR). LMD prepared the manuscript. LMD will undertake data collection (literature search, data extraction), analysis, interpretation and report writing. All co-investigators contributed to the design, analysis, interpretation and report writing. All authors read and approved the final manuscript.

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Competing interests statement:

None declared.

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Figure 1.

The COM-B Model,[38]



review only

Appendix 1: PRISMA-P Checklist

Section and Topic	Item No	Checklist Item	Page No in Protocol
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	2/7
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	3/7
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	14
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	N/A
Support:			
Sources	5a	Indicate sources of financial or other support for the review	14
Sponsor	5b	Provide name for the review funder and/or sponsor	14
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	N/A
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	4-7
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	7
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	7-10
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	10
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	10/ Appendix 2
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	11-12
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	11-12
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	11-12
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	11-12

Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	9-10
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	12
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	12-13
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ)	N/A
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	N/A
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	12-13
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	N/A
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	N/A

Source: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. *BMJ*. 2015 Jan 2;349:g7647.

Appendix 2: Search Strategy for MEDLINE (via Ovid platform)

1. chlamydia*.tw.
2. c trachomatis.tw.
3. exp Chlamydia Infections/
4. exp Chlamydia trachomatis/
5. 1 or 2 or 3 or 4
6. screen*.tw.
7. detect*.tw.
8. test.tw.
9. tests.tw.
10. testing.tw.
11. diagnos*.tw.
12. 6 or 7 or 8 or 9 or 10 or 11
13. general practice* .tw.
14. general practitioner*.tw.
15. GP.tw.
16. primary care.tw.
17. family practice.tw.
18. family practitioner*.tw.
19. family medicine.tw.
20. family physician.tw.
21. primary health care.tw.
22. primary healthcare.tw.
23. primary care nurs*.tw.
24. general practice nurs*.tw.

- 1
- 2
- 3 25. nurse practitioner*.tw.
- 4
- 5 26. 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25
- 6
- 7 27. barrier*.tw.
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- 9 28. enabler*.tw.
- 10
- 11 29. facilitator*.tw.
- 12
- 13 30. attitude*.tw.
- 14
- 15 31. feasibility.tw.
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- 17 32. 27 or 28 or 29 or 30 or 31
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- 19 33. 5 and 12 and 26 and 32
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- 21 34. limit 33 to yr="2000 – 2016"
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BMJ Open

Facilitators and barriers to chlamydia testing in general practice for young people using a theoretical model (COM-B): A systematic review protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2016-013588.R1
Article Type:	Protocol
Date Submitted by the Author:	04-Nov-2016
Complete List of Authors:	<p>McDonagh, Lorraine; University College London, Research Department of Primary Care and Population Health; University College London, National Institute for Health Research Health Protection Research Unit in Blood Borne and Sexually Transmitted Infections</p> <p>Saunders, John; Public Health England Colindale, National Chlamydia Screening Programme; University College London, National Institute for Health Research Health Protection Research Unit in Blood Borne and Sexually Transmitted Infections</p> <p>Cassell, Jacqueline; University of Brighton, Division of Primary Care and Public Health, Brighton and Sussex Medical School; University College London, National Institute for Health Research Health Protection Research Unit in Blood Borne and Sexually Transmitted Infections</p> <p>Bastaki, Hamad; University College London, Research Department of Primary Care and Population Health</p> <p>Hartney, Thomas; University College London, Research Department of Primary Care and Population Health; University College London, National Institute for Health Research Health Protection Research Unit in Blood Borne and Sexually Transmitted Infections</p> <p>Rait, Greta; University College London, Research Department of Primary Care and Population Health; University College London, National Institute for Health Research Health Protection Research Unit in Blood Borne and Sexually Transmitted Infections</p>
Primary Subject Heading:	Sexual health
Secondary Subject Heading:	General practice / Family practice, Infectious diseases, Health services research
Keywords:	chlamydia, general practice, young people, behavior change, PRIMARY CARE

SCHOLARONE™
Manuscripts

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3 **FACILITATORS AND BARRIERS TO CHLAMYDIA TESTING IN GENERAL**
4 **PRACTICE FOR YOUNG PEOPLE USING A THEORETICAL MODEL (COM-B):**
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7 **A SYSTEMATIC REVIEW PROTOCOL**
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54 **KEYWORDS:** Chlamydia; general practice; primary care; young people

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56 **WORD COUNT:** 2,472
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ABSTRACT

Introduction

Chlamydia is a key health concern, with high economic and social costs. There were over 200,000 chlamydia diagnoses made in England in 2015. The burden of chlamydia is greatest among young people where the highest prevalence rates are found. Annual testing for sexually active young people is recommended; however, many of those at risk do not receive testing. General practice has been identified as an ideal setting for testing, yet efforts to increase testing in this setting have not been effective. One theoretical model which may provide insight into the underpinnings of chlamydia testing is the Capability, Opportunity, and Motivation Model of Behaviour (COM-B model). The aim of this systematic review is to: (1) identify barriers and facilitators to chlamydia testing for young people in general practice, and (2) use a theoretical model to conduct a behavioural analysis of chlamydia testing behaviour.

Methods and analysis

Qualitative, quantitative, and mixed methods studies published after 2000 will be included. Seven databases (MEDLINE, PubMed, Embase, Informit, PsycInfo, Scopus, Web of Science) will be searched to identify peer-reviewed publications which examined barriers and facilitators to chlamydia testing in general practice. Risk of bias will be assessed using the Critical Appraisal Skills Programme. Data regarding study design and key findings will be extracted. The data will be analysed using thematic analysis and the resultant factors will be mapped onto the COM-B model components. All findings will be reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.

Ethics and dissemination

1
2
3 Ethical approval is not required. The results will be disseminated via submission for
4 publication to a peer-review journal when complete and for presentation at national and
5 international conferences. The review findings will be used to inform the development of
6 interventions to facilitate effective and efficient chlamydia testing in general practice.
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14 **Prospero registration number:** CRD42016041786
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For peer review only

INTRODUCTION

Chlamydia is a key public health concern, with great economic and social costs. There were 200,288 chlamydia diagnoses made in England in 2015,[1]. The burden of chlamydia is greatest among people aged 15-24 years where the highest prevalence rates are found,[1]. Chlamydia is often asymptomatic and can pose severe health consequences if left undiagnosed and/or untreated (i.e., pelvic inflammatory disease, infertility, ectopic pregnancy). Testing and early treatment, therefore, are an effective way to interrupt the transmission chain in the population and prevent such sequelae,[2].

Chlamydia testing in general practice

In 2015 (last complete year of STI surveillance data in England), a total of 1,538,820 chlamydia tests were conducted in 15 to 24 year olds; 298,263 (19.4%) of these were performed in general practice,[1]. The test positivity (number of positive tests divided by total number of tests) in general practice is slightly lower than the average for all tests in young people, approximately 5.9% versus 8.3%, respectively[1]. This indicates that testing in general practice reaches a slightly different risk group compared to specialist settings. Additionally, many more young people attend general practice compared to sexual health clinics over the course of a year. Hence, there is considerable potential to reach more young people with testing in general practice compared to other settings. In the UK, STI testing is funded by local authorities (local government) and there is currently a drive to shift high volume, low cost testing (i.e., chlamydia testing in asymptomatic young people) away from expensive specialist settings and into primary care (e.g., general practice)[3]. This would free up capacity in specialist settings to see more complex patients and put onus on general practice to do more testing in asymptomatic young people.

1
2
3 General practice is one logical setting for chlamydia testing for a variety of reasons.
4
5 Over 60% of young people attend general practice annually,[4, 5]. Young people have
6
7 reported a preference to receive testing and testing results from a general practitioner,[6-9].
8
9 Higher rates of positivity have been found, particularly for males, in general practice
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11 compared to non-healthcare settings such as universities,[3, 10]. Finally, regular screening is
12
13 easier to maintain in this setting, due to patients attending for other reasons, which is
14
15 necessary for continued transmission reduction,[10].
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20 21 **Barriers and facilitators to chlamydia testing**

22 Annual testing for sexually active young people is recommended in several countries
23
24 including Australia, Denmark, England, Norway, Sweden, and the USA,[11-15].
25
26 Unfortunately, however, many of those at risk do not receive testing. Lack of testing has been
27
28 attributed to barriers at the patient level, provider level, and system level. In a recent narrative
29
30 review of chlamydia testing in general practice, the most common barriers identified were the
31
32 social context of testing (i.e., stigma), poor knowledge/training, and time constraints,[16].
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34 However, the review was conducted using a narrative approach, and thus lacks the rigorous
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36 methodological techniques of the systematic review. It is possible that potentially relevant
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38 studies were missed.
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43 To overcome the barriers to testing and explore the facilitators, numerous
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45 interventions using a variety of strategies have been conducted,[17, 18]. The evidence for
46
47 their effectiveness is mixed. For those that have been reported as being effective, the effects
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49 tend to be modest,[19, 20] or demonstrate little clinical significance,[21]. One possible
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51 explanation for these disappointing results is the lack of input from theories of behaviour.
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55 56 **The role of theory**

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3 It is increasingly recognised that an understanding of behaviour and behaviour change
4 is required to maximise the effectiveness of interventions,[22, 23]. Essentially, in order to
5 change a particular behaviour (such as increase chlamydia testing), it is necessary to have a
6 theoretical understanding of that behaviour,[24, 25]. Applying theory to intervention design
7 allows researchers to explain and predict specific behaviours in terms of why, when, and how
8 they occur, as well as which factors should be targeted to in order to alter them. There are
9 numerous theories of behaviour and it is unclear which one to choose. A further issue is that,
10 once a suitable theory is identified, it can be difficult to decipher how to apply it to the
11 development of an intervention,[26].
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23 One promising overarching theory of behaviour, and basis for designing interventions
24 aimed at behaviour change, is the COM-B model (capability, opportunity, motivation,
25 behaviour),[27]. The COM-B model proposes that behaviour (B) is the result of an interaction
26 between three components; capability (C), opportunity (O) and motivation (M). Behaviour
27 change, therefore, requires a change in one or more of these components. The COM-B model
28 lies at the centre of the Behaviour Change Wheel (a tool kit for designing behaviour change
29 interventions,[27]) and is the starting point of intervention development. Capability can be
30 psychological (e.g., knowledge) or physical (e.g., skills); opportunity can be social (e.g.,
31 societal influences) or physical (e.g., environmental resources); motivation can be automatic
32 (e.g., emotion) or reflective (e.g., beliefs, intentions). In other words, for a person to engage
33 in a specific behaviour, they need to: (1) be psychologically and physically able to do the
34 behaviour; (2) have the physical and social opportunity to do the behaviour; and (3) want or
35 need to do the behaviour. The model is illustrated in Figure 1.
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51 The COM-B model has not yet been applied to chlamydia testing, however, it has
52 been successfully applied in other health behaviour contexts,[28-30] and has been used to as
53 basis for developing effective interventions,[31-33]. The benefit of employing the COM-B
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3 model to chlamydia testing is that several distinct explanatory components are outlined; thus,
4
5 additional potential influences on behaviour can be considered which is essential for the
6
7 development of an intervention. Furthermore, once the COM-B model has been used to
8
9 conduct an in-depth theoretically-based analysis of the behaviour in question, it can be
10
11 ultimately used to identify the mediators and moderators of behaviour to be targeted by an
12
13 intervention with the Behaviour Change Wheel,[26].
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16 17 18 **Research aims**

19
20 The aim of this systematic review is to identify the barriers and facilitators to chlamydia
21
22 testing for young people in general practice and to use the COM-B model to conduct a
23
24 behavioural analysis of chlamydia testing. The specific research questions of this systematic
25
26 review are:
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28

- 29 1. What are the facilitators and barriers to chlamydia testing for young people in general
30 practice?
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- 32 2. What are the facilitators and barriers to chlamydia testing for primary care providers
33 in general practice?
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- 35 3. How do identified facilitators and barriers of chlamydia testing for young people in
36 general practice map on to a theoretical model of behaviour change?
37
- 38 4. How do identified facilitators and barriers of chlamydia testing for primary care
39 providers in general practice map on to a theoretical model of behaviour change?
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49 **METHODS AND ANALYSIS**

50 This systematic review will be conducted in accordance with the Preferred Reporting Items
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52 for Systematic Reviews and Meta-Analyses (PRISMA) Statement guidelines,[34]. The
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54 PRISMA-Protocol checklist is presented in Appendix 1. In addition, the relevant literature for
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3 reporting of qualitative studies within systematic reviews will be consulted to ensure all
4 necessary information is provided, [35, 36]. This review is registered with the international
5 database of prospectively registered systematic reviews in health and social care
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10 (PROSPERO; registration number CRD42016041786; available at
11
12 http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42016041786).
13

14 15 16 **Eligibility criteria**

17 To be included in the review, papers will have to meet the following PICOS (Population,
18
19 Intervention, Context, Outcomes and Study design) elements:
20
21

22 23 24 25 1. Population

26 27 *Inclusion criteria:*

- 28 – Young men and women (aged 15-24 years) and primary care providers (general
29 practitioners, practice nurses, nurse practitioners).
30
31
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33 34 *Exclusion criteria:*

- 35 – Studies focusing exclusively on commercial sex workers, incarcerated people, people
36 living with HIV, victims of sexual or domestic abuse or violence, intravenous drug
37 users, and individuals with no fixed address as these groups have distinct needs
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42 beyond the scope of the review.
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45 46 47 2. Intervention

48 The issue to be reviewed is opportunistic and systematic chlamydia testing for young people
49 in general practice. Opportunistic testing will be defined as the offer of a diagnostic test to
50 people attending general practice during a consultation for another reason. Systematic testing
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52 will be defined by the use of existing population registers to invite the target group to submit
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self-collected samples by post. A barrier will be defined as a factor that obstructs or prevents chlamydia testing; a facilitator will be defined as a factor that supports or promotes chlamydia testing.

Inclusion criteria:

- Randomized and non-randomized controlled trials, pre- and post-test designs, non-experiment observational (cross-sectional, case-series, case studies), and qualitative papers (interviews, focus groups).

Exclusion criteria:

- Exclusively set outside of general practice, exclusively focused on partner notification, campaigns exclusively focused on health promotion, and testing for diagnostic purposes when symptoms are present.

3. Context

Inclusion criteria:

- Studies conducted in Australia, Denmark, Ireland, Netherlands, New Zealand, and the UK as the model of delivering healthcare in general practice is comparable.

Exclusion criteria:

- Studies conducted in countries where the general practice setting is not comparable to that of the UK (e.g., USA, Canada).

4. Outcomes

Primary outcomes

- Young people: Perceived facilitators to chlamydia testing, perceived barriers to chlamydia testing, views towards chlamydia testing, and acceptability of chlamydia testing.

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3 – Primary care providers: Perceived facilitators to chlamydia testing, perceived barriers
4 to chlamydia testing, views towards chlamydia testing, and acceptability of chlamydia
5 testing.
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10 *Secondary outcomes*

11 Classification of the identified barriers and facilitators into the sub-components of the COM-
12 B model: psychological capability, physical capability, social opportunity, physical
13 opportunity, automatic motivation, and reflective motivation.
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21 5. Study design

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23 *Inclusion criteria:*

- 24 – Quantitative (i.e., cross-sectional, case-series, and case studies), qualitative, and
25 mixed method studies.
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30 *Exclusion criteria:*

- 31 – Commentary or opinion publications that do not present new data.
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36 **Information sources**

37 The review will access both published and unpublished material by searching literature
38 sources listed below between January 2000 and March 2016. Pre-2000 studies will be
39 excluded as Nucleic Acid Amplification Tests (NAATs) of urine samples were introduced
40 around this time, thus widening testing to non-clinical settings. The following databases will
41 be searched: MEDLINE, Pubmed, Embase, Informit, Web of Science, PsycINFO, and
42 Scopus. Relevant articles will also be identified from a hand search of reference lists of
43 included articles.
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56 **Search strategy**
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3 Medical Subject Headings (MeSH), subject headings and keywords will be created by using
4 language that describes facilitators and barriers to chlamydia testing in general practice.
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7 Boolean combinations will create more specific searches. Initial scoping searches will be
8 conducted to refine the search strategy. For example, key publications in the field will be
9 identified, and searches run to ensure these are captured. The three sets of search terms relate
10 to the context (general practice), the intervention (chlamydia testing), and outcomes (barriers
11 and facilitators). The search strategy presented in Appendix 2 will be used to search
12 MEDLINE, using an Ovid platform. Search terms will be modified for other databases where
13 subject heading indexing differ from the terms used in MEDLINE.
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24 25 **Data extraction and management** 26

27 Data will be extracted from all full text studies that fulfil the inclusion criteria. The reviewers
28 will characterise the research design used in each study, including study population, sample
29 size, response rate (if described), randomization (if RCT), presence or absence of a
30 comparison group, data collection methods, and key findings (primary/secondary outcomes).
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34 A standardised framework will be devised and used to record the aims,
35 methodological characteristics, main findings and relevance of each study. All identified
36 references will be stored in Endnote. Data extraction will be undertaken by one reviewer
37 (LMD) and checked by a second reviewer (HB/TH). Any discrepancies will be resolved by
38 discussion between two researchers or adjudication by a third reviewer (GR/JC) when
39 necessary. If required, primary authors will be contacted for additional data.
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51 All studies that meet the inclusion criteria will be described in terms of:
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- 53 – Design and quality, data collection methods, modes and techniques; validity of tools;
54 qualitative, statistical and other analyses
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- 3 – Participants, demographic characteristics (e.g., age, ethnicity)
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- 5 – Setting and recruitment methods, details of modes of delivery and any other aspects of
- 6
- 7 content
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- 9
- 10 – Theoretical framework employed in study (if any)
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- 13

14 The following data will be extracted:

- 15
- 16 1. Data relating to young people:
- 17
- 18 – Perceived facilitators to chlamydia testing, perceived barriers to chlamydia
- 19 testing, reasons for accepting or refusing the offer of chlamydia testing, and
- 20 acceptability of chlamydia testing in general practice.
- 21
- 22
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- 25 2. Data relating to primary care providers:
- 26
- 27 – Perceived facilitators to chlamydia testing, perceived barriers to chlamydia
- 28 testing, provider reasons for providing chlamydia testing to young people, and
- 29 acceptability of chlamydia testing in general practice.
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36 **Risk of bias (quality) assessment**

37 The quality of each paper will be assessed independently by two reviewers (LMD and
38 HB/TH). Any discrepancies will be resolved by consensus and, if necessary, a third party will
39 be consulted. Each paper will be assessed using criteria based on the Critical Appraisal Skills
40 Programme,[37]. Individual studies will be classified as primary (high quality studies
41 providing theoretical insight into sexual behaviour or thorough descriptions of particular
42 contexts) and secondary (lower quality studies that had simple, non-detailed descriptions or
43 do not support statements with evidence). The critical appraisal process will not be used to
44 exclude papers prior to the synthesis; rather, it will be used to provide a context for the
45 interpretation of the synthesised findings.
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Data synthesis and analysis

Individual study characteristics and outcomes will be summarised and presented in an evidence table. Thematic analysis, employing expert guidelines,[38] will be used to identify prominent/recurrent themes in the literature. The use of the statistical software package NVivo11 will aid in managing the coding of the data set, with each code (or node) representing the emergent themes, e.g., “education”. The frequency of themes as well as their explanatory value will be assessed. The themes will be refined through discussion and the use of constant comparison within and between codes to ensure that they accurately reflect the material.

Finally, a behavioural analysis of chlamydia testing behaviour will be conducted. Specifically, the identified themes will be classified into the six sub-components of the COM-B model (psychological capability, physical capability, social opportunity, physical opportunity, automatic motivation, and reflective motivation; see Figure 1). Data classification will be conducted by one reviewer (LMD) in consultation with members of the review team (JS, JC, HB, TH, and GR), employing guidelines set out by Michie and colleagues,[27]. Any discrepancies will be resolved by consensus.

DISCUSSION AND DISSEMINATION

To the authors’ knowledge, this is the first systematic review to conduct a theoretical behavioural analysis of barriers and facilitators to chlamydia testing for young people in general practice. A theoretically-based framework will be generated which will provide a greater insight into the complexities of chlamydia testing. The findings will have relevance to healthcare professionals, policy-makers and commissioners in informing how best to improve the sexual health of young people. Importantly, the results will be integral to inform the

1
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3 development of interventions that will facilitate effective and efficient access to care and
4
5 treatment for chlamydia in primary care, with the aim of reducing morbidity and transmission
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7 of chlamydia.
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10 The review results will be disseminated via submission for publication to a peer-
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12 review journal when complete and submissions to be presented at national and international
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14 conferences (where eligible). Furthermore, lay and scientific summaries will be produced for
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16 wider dissemination (e.g., via newsletters, blogs, and organisation meetings).
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Authors' contributions:

GR and JC designed the study and obtained funding. LMD developed and refined the study protocol with contributions from all co-authors (JS, JC, HB, TH, and GR). LMD prepared the manuscript. LMD will undertake data collection (literature search, data extraction), analysis, interpretation and report writing. All co-investigators contributed to the design, analysis, interpretation and report writing. All authors read and approved the final manuscript.

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Competing interests statement:

None declared.

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Figure 1.

The COM-B Model,[26]

For peer review only

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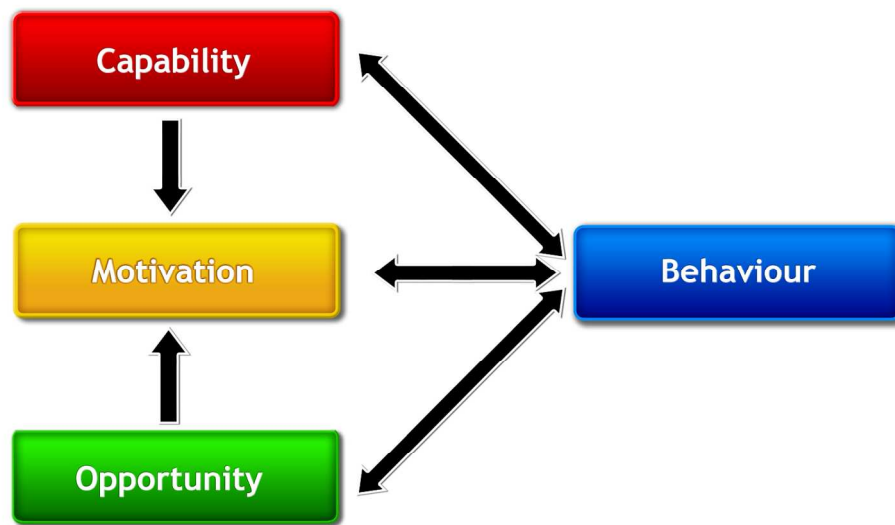


Figure 1.!! † The COM-B Model,[26]
The model is illustrated in Fi
150x82mm (300 x 300 DPI)

review only

Appendix 1: PRISMA-P Checklist

Section and Topic	Item No	Checklist Item	Page No in Protocol
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	2/7
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	3/8
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	15
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	N/A
Support:			
Sources	5a	Indicate sources of financial or other support for the review	15
Sponsor	5b	Provide name for the review funder and/or sponsor	15
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	N/A
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	4-7
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	7
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	8-10
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	10
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	10-11/ Appendix 2
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	11-12
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	11-12
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	11-12
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	11-12

Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	9-10
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	12
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	13
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ)	N/A
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	N/A
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	13
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	N/A
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	N/A

Source: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. *BMJ*. 2015 Jan 2;349:g7647.

BMJ Open

Facilitators and barriers to chlamydia testing in general practice for young people using a theoretical model (COM-B): A systematic review protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2016-013588.R2
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Date Submitted by the Author:	20-Jan-2017
Complete List of Authors:	McDonagh, Lorraine; University College London, Research Department of Primary Care and Population Health; University College London, National Institute for Health Research Health Protection Research Unit in Blood Borne and Sexually Transmitted Infections Saunders, John; Public Health England Colindale, National Chlamydia Screening Programme; University College London, National Institute for Health Research Health Protection Research Unit in Blood Borne and Sexually Transmitted Infections Cassell, Jacqueline; University of Brighton, Division of Primary Care and Public Health, Brighton and Sussex Medical School; University College London, National Institute for Health Research Health Protection Research Unit in Blood Borne and Sexually Transmitted Infections Bastaki, Hamad; University College London, Research Department of Primary Care and Population Health Hartney, Thomas; University College London, Research Department of Primary Care and Population Health; University College London, National Institute for Health Research Health Protection Research Unit in Blood Borne and Sexually Transmitted Infections Rait, Greta; University College London, Research Department of Primary Care and Population Health; University College London, National Institute for Health Research Health Protection Research Unit in Blood Borne and Sexually Transmitted Infections
Primary Subject Heading:	Sexual health
Secondary Subject Heading:	General practice / Family practice, Infectious diseases, Health services research
Keywords:	chlamydia, general practice, young people, behavior change, PRIMARY CARE

SCHOLARONE™
Manuscripts

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3 **FACILITATORS AND BARRIERS TO CHLAMYDIA TESTING IN GENERAL**
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5 **PRACTICE FOR YOUNG PEOPLE USING A THEORETICAL MODEL (COM-B):**
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7 **A SYSTEMATIC REVIEW PROTOCOL**
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12 Lorraine K. McDonagh^{1,2}

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53 **KEYWORDS:** Chlamydia; general practice; primary care; young people

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55 **WORD COUNT:** 2,472
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ABSTRACT

Introduction

Chlamydia is a key health concern, with high economic and social costs. There were over 200,000 chlamydia diagnoses made in England in 2015. The burden of chlamydia is greatest among young people where the highest prevalence rates are found. Annual testing for sexually active young people is recommended; however, many of those at risk do not receive testing. General practice has been identified as an ideal setting for testing, yet efforts to increase testing in this setting have not been effective. One theoretical model which may provide insight into the underpinnings of chlamydia testing is the Capability, Opportunity, and Motivation Model of Behaviour (COM-B model). The aim of this systematic review is to: (1) identify barriers and facilitators to chlamydia testing for young people in general practice, and (2) use a theoretical model to conduct a behavioural analysis of chlamydia testing behaviour.

Methods and analysis

Qualitative, quantitative, and mixed methods studies published after 2000 will be included. Seven databases (MEDLINE, PubMed, Embase, Informit, PsycInfo, Scopus, Web of Science) will be searched to identify peer-reviewed publications which examined barriers and facilitators to chlamydia testing in general practice. Risk of bias will be assessed using the Critical Appraisal Skills Programme. Data regarding study design and key findings will be extracted. The data will be analysed using thematic analysis and the resultant factors will be mapped onto the COM-B model components. All findings will be reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.

Ethics and dissemination

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3 Ethical approval is not required. The results will be disseminated via submission for
4 publication to a peer-review journal when complete and for presentation at national and
5 international conferences. The review findings will be used to inform the development of
6 interventions to facilitate effective and efficient chlamydia testing in general practice.
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14 **Prospero registration number:** CRD42016041786
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INTRODUCTION

Chlamydia is a key public health concern, with great economic and social costs. There were 200,288 chlamydia diagnoses made in England in 2015,[1]. The burden of chlamydia is greatest among people aged 15-24 years where the highest prevalence rates are found,[1]. Chlamydia is often asymptomatic and can pose severe health consequences if left undiagnosed and/or untreated (i.e., pelvic inflammatory disease, infertility, ectopic pregnancy). Testing and early treatment, therefore, are an effective way to interrupt the transmission chain in the population and prevent such sequelae,[2].

Chlamydia testing in general practice

In 2015 (last complete year of STI surveillance data in England), a total of 1,538,820 chlamydia tests were conducted in 15 to 24 year olds; 298,263 (19.4%) of these were performed in general practice,[1]. The test positivity (number of positive tests divided by total number of tests) in general practice is slightly lower than the average for all tests in young people, approximately 5.9% versus 8.3%, respectively[1]. This indicates that testing in general practice reaches a slightly different risk group compared to specialist settings. Additionally, many more young people attend general practice compared to sexual health clinics over the course of a year. Hence, there is considerable potential to reach more young people with testing in general practice compared to other settings. In the UK, STI testing is funded by local authorities (local government) and there is currently a drive to shift high volume, low cost testing (i.e., chlamydia testing in asymptomatic young people) away from expensive specialist settings and into primary care (e.g., general practice)[3]. This would free up capacity in specialist settings to see more complex patients and put onus on general practice to do more testing in asymptomatic young people.

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General practice is one logical setting for chlamydia testing for a variety of reasons. Over 60% of young people attend general practice annually,[4, 5]. Young people have reported a preference to receive testing and testing results from a general practitioner,[6-9]. Higher rates of positivity have been found, particularly for males, in general practice compared to non-healthcare settings such as universities,[3, 10]. Finally, regular screening is easier to maintain in this setting, due to patients attending for other reasons, which is necessary for continued transmission reduction,[10].

Barriers and facilitators to chlamydia testing

Annual testing for sexually active young people is recommended in several countries including Australia, Denmark, England, Norway, Sweden, and the USA,[11-15]. Unfortunately, however, many of those at risk do not receive testing. Lack of testing has been attributed to barriers at the patient level, provider level, and system level. In a recent narrative review of chlamydia testing in general practice, the most common barriers identified were the social context of testing (i.e., stigma), poor knowledge/training, and time constraints,[16]. However, the review was conducted using a narrative approach, and thus lacks the rigorous methodological techniques of the systematic review. It is possible that potentially relevant studies were missed.

To overcome the barriers to testing and explore the facilitators, numerous interventions using a variety of strategies have been conducted,[17, 18]. The evidence for their effectiveness is mixed. For those that have been reported as being effective, the effects tend to be modest,[19, 20] or demonstrate little clinical significance,[21]. One possible explanation for these disappointing results is the lack of input from theories of behaviour.

The role of theory

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3 It is increasingly recognised that an understanding of behaviour and behaviour change
4 is required to maximise the effectiveness of interventions,[22, 23]. Essentially, in order to
5 change a particular behaviour (such as increase chlamydia testing), it is necessary to have a
6 theoretical understanding of that behaviour,[24, 25]. Applying theory to intervention design
7 allows researchers to explain and predict specific behaviours in terms of why, when, and how
8 they occur, as well as which factors should be targeted to in order to alter them. There are
9 numerous theories of behaviour and it is unclear which one to choose. A further issue is that,
10 once a suitable theory is identified, it can be difficult to decipher how to apply it to the
11 development of an intervention,[26].
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23 One promising overarching theory of behaviour, and basis for designing interventions
24 aimed at behaviour change, is the COM-B model (capability, opportunity, motivation,
25 behaviour),[27]. The COM-B model proposes that behaviour (B) is the result of an interaction
26 between three components; capability (C), opportunity (O) and motivation (M). Behaviour
27 change, therefore, requires a change in one or more of these components. The COM-B model
28 lies at the centre of the Behaviour Change Wheel (a tool kit for designing behaviour change
29 interventions,[27]) and is the starting point of intervention development. Capability can be
30 psychological (e.g., knowledge) or physical (e.g., skills); opportunity can be social (e.g.,
31 societal influences) or physical (e.g., environmental resources); motivation can be automatic
32 (e.g., emotion) or reflective (e.g., underlying beliefs, intentions [25-27]). In other words, for a
33 person to engage in a specific behaviour, they need to: (1) be psychologically and physically
34 able to do the behaviour; (2) have the physical and social opportunity to do the behaviour;
35 and (3) want or need to do the behaviour. The model is illustrated in Figure 1.
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52 The COM-B model has not yet been applied to chlamydia testing, however, it has
53 been successfully applied in other health behaviour contexts,[28-35] and has been used to as
54 basis for developing effective interventions,[36-39]. The benefit of employing the COM-B
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3 model to chlamydia testing is that several distinct explanatory components are outlined; thus,
4
5 additional potential influences on behaviour can be considered which is essential for the
6
7 development of an intervention. Furthermore, once the COM-B model has been used to
8
9 conduct an in-depth theoretically-based analysis of the behaviour in question, it can be
10
11 ultimately used to identify the mediators and moderators of behaviour to be targeted by an
12
13 intervention with the Behaviour Change Wheel,[26].
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16 17 18 **Research aims**

19
20 The aim of this systematic review is to identify the barriers and facilitators to chlamydia
21
22 testing for young people in general practice and to use the COM-B model to conduct a
23
24 behavioural analysis of chlamydia testing. The specific research questions of this systematic
25
26 review are:
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- 29
30 1. What are the facilitators and barriers to chlamydia testing for young people in general
31
32 practice?
- 33
34 2. What are the facilitators and barriers to chlamydia testing for primary care providers
35
36 in general practice?
- 37
38 3. How do identified facilitators and barriers of chlamydia testing for young people in
39
40 general practice map on to a theoretical model of behaviour change?
- 41
42 4. How do identified facilitators and barriers of chlamydia testing for primary care
43
44 providers in general practice map on to a theoretical model of behaviour change?
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49 50 **METHODS AND ANALYSIS**

51
52 This systematic review will be conducted in accordance with the Preferred Reporting Items
53
54 for Systematic Reviews and Meta-Analyses (PRISMA) Statement guidelines,[40]. The
55
56 PRISMA-Protocol checklist is presented in Appendix 1. In addition, the relevant literature for
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2
3 reporting of qualitative studies within systematic reviews will be consulted to ensure all
4 necessary information is provided, [41, 42]. This review is registered with the international
5 database of prospectively registered systematic reviews in health and social care
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10 (PROSPERO; registration number CRD42016041786; available at
11
12 http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42016041786).

16 **Eligibility criteria**

17
18 To be included in the review, papers will have to meet the following PICOS (Population,
19 Intervention, Context, Outcomes and Study design) elements:
20
21

25 1. Population

27 *Inclusion criteria:*

- 29 – Young men and women (aged 15-24 years) and primary care providers (general
30 practitioners, practice nurses, nurse practitioners).

34 *Exclusion criteria:*

- 36 – Studies focusing exclusively on commercial sex workers, incarcerated people, people
37 living with HIV, victims of sexual or domestic abuse or violence, intravenous drug
38 users, and individuals with no fixed address as these groups have distinct needs
39 beyond the scope of the review. Studies which partially include these populations
40 (i.e., as part of a general population sample) will be included, however the sample
41 composition will be discussed when interpreting their findings.
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51 2. Intervention

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53 The issue to be reviewed is opportunistic and systematic chlamydia testing for young people
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55 in general practice. Opportunistic testing will be defined as the offer of a diagnostic test to
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3 people attending general practice during a consultation for another reason. Systematic testing
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5 will be defined by the use of existing population registers to invite the target group to submit
6
7 self-collected samples by post. A barrier will be defined as a factor that obstructs or prevents
8
9 chlamydia testing; a facilitator will be defined as a factor that supports or promotes
10
11 chlamydia testing.
12

13
14 *Inclusion criteria:*

- 15
16 – Randomized and non-randomized controlled trials, pre- and post-test designs, non-
17
18 experiment observational (cross-sectional, case-series, case studies), and qualitative
19
20 papers (interviews, focus groups).
21

22
23 *Exclusion criteria:*

- 24
25 – Exclusively set outside of general practice, exclusively focused on partner
26
27 notification, campaigns exclusively focused on health promotion, and testing for
28
29 diagnostic purposes when symptoms are present.
30
31

32
33
34 3. Context

35
36 *Inclusion criteria:*

- 37
38 – Studies conducted in Australia, Denmark, Ireland, Netherlands, New Zealand, and the
39
40 UK as the model of delivering healthcare in general practice is comparable.
41

42
43 *Exclusion criteria:*

- 44
45 – Studies conducted in countries where the general practice setting is not comparable to
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47 that of the UK (e.g., USA, Canada).
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51 4. Outcomes

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53 *Primary outcomes*
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- Young people: Perceived facilitators to chlamydia testing, perceived barriers to chlamydia testing, views towards chlamydia testing, and acceptability of chlamydia testing.
- Primary care providers: Perceived facilitators to chlamydia testing, perceived barriers to chlamydia testing, views towards chlamydia testing, and acceptability of chlamydia testing.

Secondary outcomes

Classification of the identified barriers and facilitators into the sub-components of the COM-B model: psychological capability, physical capability, social opportunity, physical opportunity, automatic motivation, and reflective motivation.

5. Study design

Inclusion criteria:

- Quantitative (i.e., cross-sectional, case-series, and case studies), qualitative, and mixed method studies.

Exclusion criteria:

- Commentary or opinion publications that do not present new data.

Information sources

The review will access both published and unpublished material by searching literature sources listed below between January 2000 and March 2016. Pre-2000 studies will be excluded as Nucleic Acid Amplification Tests (NAATs) of urine samples were introduced around this time, thus widening testing to non-clinical settings. The following databases will be searched: MEDLINE, Pubmed, Embase, Informit, Web of Science, PsycINFO, and

1
2
3 Scopus. Relevant articles will also be identified from a hand search of reference lists of
4
5 included articles.
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9 10 **Search strategy**

11 Medical Subject Headings (MeSH), subject headings and keywords will be created by using
12
13 language that describes facilitators and barriers to chlamydia testing in general practice.
14
15 Boolean combinations will create more specific searches. Initial scoping searches will be
16
17 conducted to refine the search strategy. For example, key publications in the field will be
18
19 identified, and searches run to ensure these are captured. The three sets of search terms relate
20
21 to the context (general practice), the intervention (chlamydia testing), and outcomes (barriers
22
23 and facilitators). The search strategy presented in Appendix 2 will be used to search
24
25 MEDLINE, using an Ovid platform. Search terms pertaining to behaviour and behaviour
26
27 change theories which will be piloted are presented in Appendix 3. Search terms will be
28
29 modified for other databases where subject heading indexing differ from the terms used in
30
31 MEDLINE.
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39 **Data extraction and management**

40 Data will be extracted from all full text studies that fulfil the inclusion criteria. The reviewers
41
42 will characterise the research design used in each study, including study population, sample
43
44 size, response rate (if described), randomization (if RCT), presence or absence of a
45
46 comparison group, data collection methods, and key findings (primary/secondary outcomes).
47
48

49 A standardised framework will be devised and used to record the aims,
50
51 methodological characteristics, main findings and relevance of each study. All identified
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53 references will be stored in Endnote. Data extraction will be undertaken by one reviewer
54
55 (LMD) and checked by a second reviewer (HB/TH). Any discrepancies will be resolved by
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2
3 discussion between two researchers or adjudication by a third reviewer (GR/JC) when
4
5 necessary. If required, primary authors will be contacted for additional data.
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9
10 All studies that meet the inclusion criteria will be described in terms of:

- 11 – Design and quality, data collection methods, modes and techniques; validity of tools;
12 qualitative, statistical and other analyses
- 13 – Participants, demographic characteristics (e.g., age, ethnicity)
- 14 – Setting and recruitment methods, details of modes of delivery and any other aspects of
15 content
- 16 – Theoretical framework employed in study (if any)
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26
27 The following data will be extracted:

- 28 1. Data relating to young people:
 - 29 – Perceived facilitators to chlamydia testing, perceived barriers to chlamydia
30 testing, reasons for accepting or refusing the offer of chlamydia testing, and
31 acceptability of chlamydia testing in general practice.
- 32 2. Data relating to primary care providers:
 - 33 – Perceived facilitators to chlamydia testing, perceived barriers to chlamydia
34 testing, provider reasons for providing chlamydia testing to young people, and
35 acceptability of chlamydia testing in general practice.
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50 **Risk of bias (quality) assessment**

51 The quality of each paper will be assessed independently by two reviewers (LMD and
52 HB/TH). Any discrepancies will be resolved by consensus and, if necessary, a third party will
53
54 be consulted. Each paper will be assessed using criteria based on the Critical Appraisal Skills
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3 Programme,[43]. Individual studies will be classified as primary (high quality studies
4 providing theoretical insight into sexual behaviour or thorough descriptions of particular
5 contexts) and secondary (lower quality studies that had simple, non-detailed descriptions or
6 do not support statements with evidence). The critical appraisal process will not be used to
7 exclude papers prior to the synthesis; rather, it will be used to provide a context for the
8 interpretation of the synthesised findings.
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19 **Data synthesis and analysis**

20 Individual study characteristics and outcomes will be summarised and presented in an
21 evidence table. Thematic analysis, employing expert guidelines,[44] will be used to identify
22 prominent/recurrent themes in the literature. The use of the statistical software package
23 NVivo11 will aid in managing the coding of the data set, with each code (or node)
24 representing the emergent themes, e.g., “education”. The frequency of themes as well as their
25 explanatory value will be assessed. The themes will be refined through discussion and the use
26 of constant comparison within and between codes to ensure that they accurately reflect the
27 material.
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38 Finally, a behavioural analysis of chlamydia testing behaviour will be conducted.
39 Specifically, the identified themes will be classified into the six sub-components of the COM-
40 B model (psychological capability, physical capability, social opportunity, physical
41 opportunity, automatic motivation, and reflective motivation; see Figure 1). Data
42 classification will be conducted by one reviewer (LMD) in consultation with members of the
43 review team (JS, JC, HB, TH, and GR), employing guidelines set out by Michie and
44 colleagues,[27]. Any discrepancies will be resolved by consensus.
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56 **DISCUSSION AND DISSEMINATION**

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3 To the authors' knowledge, this is the first systematic review to conduct a theoretical
4 behavioural analysis of barriers and facilitators to chlamydia testing for young people in
5 general practice. A theoretically-based framework will be generated which will provide a
6 greater insight into the complexities of chlamydia testing. The findings will have relevance to
7 healthcare professionals, policy-makers and commissioners in informing how best to improve
8 the sexual health of young people. Importantly, the results will be integral to inform the
9 development of interventions that will facilitate effective and efficient access to care and
10 treatment for chlamydia in primary care, with the aim of reducing morbidity and transmission
11 of chlamydia.
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23 The review results will be disseminated via submission for publication to a peer-
24 review journal when complete and submissions to be presented at national and international
25 conferences (where eligible). Furthermore, lay and scientific summaries will be produced for
26 wider dissemination (e.g., via newsletters, blogs, and organisation meetings).
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Authors' contributions:

GR and JC designed the study and obtained funding. LMD developed and refined the study protocol with contributions from all co-authors (JS, JC, HB, TH, and GR). LMD prepared the manuscript. LMD will undertake data collection (literature search, data extraction), analysis, interpretation and report writing. All co-investigators contributed to the design, analysis, interpretation and report writing. All authors read and approved the final manuscript.

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Competing interests statement:

None declared.

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Figure 1.

The COM-B Model,[26]

For peer review only

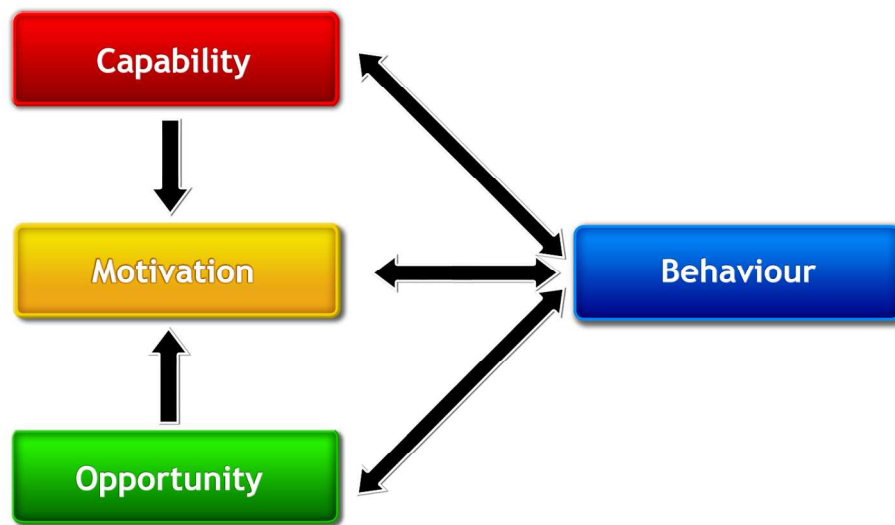


Figure 1.!! † The COM-B Model,[26]
The model is illustrated in Fi
150x82mm (300 x 300 DPI)

review only

Appendix 1: PRISMA-P Checklist

Section and Topic	Item No	Checklist Item	Page No in Protocol
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	2/7
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	3/8
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	15
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	N/A
Support:			
Sources	5a	Indicate sources of financial or other support for the review	15
Sponsor	5b	Provide name for the review funder and/or sponsor	15
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	N/A
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	4-7
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	7
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	8-10
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	10
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	11/ Append. 2-3
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	11-12
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	11-12
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	11-12
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	11-12

Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	9-10
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	12-13
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	13
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ)	N/A
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	N/A
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	13
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	N/A
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	N/A

Source: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. *BMJ*. 2015 Jan 2;349:g7647.

Appendix 2: Search Strategy for MEDLINE (via Ovid platform)

1. chlamydia*.tw.
2. c trachomatis.tw.
3. exp Chlamydia Infections/
4. exp Chlamydia trachomatis/
5. 1 or 2 or 3 or 4
6. screen*.tw.
7. detect*.tw.
8. test.tw.
9. tests.tw.
10. testing.tw.
11. diagnos*.tw.
12. 6 or 7 or 8 or 9 or 10 or 11
13. general practice* .tw.
14. general practitioner*.tw.
15. GP.tw.
16. primary care.tw.
17. family practice.tw.
18. family practitioner*.tw.
19. family medicine.tw.
20. family physician.tw.
21. primary health care.tw.
22. primary healthcare.tw.
23. primary care nurs*.tw.
24. general practice nurs*.tw.

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- 4 25. nurse practitioner*.tw.
- 5
- 6 26. 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25
- 7
- 8 27. barrier*.tw.
- 9
- 10 28. enabler*.tw.
- 11
- 12 29. facilitator*.tw.
- 13
- 14 30. attitude*.tw.
- 15
- 16 31. feasibility.tw.
- 17
- 18 32. 27 or 28 or 29 or 30 or 31
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- 20 33. 5 and 12 and 26 and 32
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- 22 34. limit 33 to yr="2000 – 2016"
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Appendix 3: Search terms for behaviour and behaviour change theories

1. acculturation theory
2. AIDS risk reduction model
3. behavior change
4. behavior change model
5. behavior change theories
6. behavior change theory
7. behavior change wheel
8. behavior economic theories
9. behavior modification
10. behavior theories
11. behavioral intervention
12. behavioral interventions
13. behaviour change
14. behaviour change model
15. behaviour change theories
16. behaviour change theory
17. behaviour change wheel
18. behaviour economic theories
19. behaviour modification
20. behaviour theories
21. behavioural intervention
22. behavioural interventions
23. capability
24. communication theory

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- 3
- 4 25. community organisation theory
- 5
- 6 26. community organization theory
- 7
- 8 27. consumer information processing model
- 9
- 10 28. control theory
- 11
- 12 29. critical consciousness
- 13
- 14 30. cultural change
- 15
- 16 31. cultural changes
- 17
- 18 32. decisional balance theory
- 19
- 20 33. ecological model
- 21
- 22 34. ecological perspective
- 23
- 24 35. empowerment theory
- 25
- 26 36. enculturation theory
- 27
- 28 37. exchange theory
- 29
- 30 38. fear arousal theory
- 31
- 32 39. goal setting theory
- 33
- 34 40. goal theory
- 35
- 36 41. group level effect
- 37
- 38 42. group level effects
- 39
- 40 43. habit theory
- 41
- 42 44. health behavior theory
- 43
- 44 45. health behaviour theory
- 45
- 46 46. health belief model
- 47
- 48 47. health promotion theories
- 49
- 50 48. health promotion theory
- 51
- 52 49. innovation-decision process
- 53
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- 4 50. interactionist model
- 5
- 6 51. intrapersonal theory
- 7
- 8 52. intrinsic motivation theories
- 9
- 10 53. mediation effects on behavior
- 11
- 12 54. mediation effects on behaviour
- 13
- 14 55. motivation
- 15
- 16 56. multicomponent stage model
- 17
- 18 57. natural recovery
- 19
- 20 58. normative change
- 21
- 22 59. normative changes
- 23
- 24 60. operant learning theory
- 25
- 26 61. operant theory
- 27
- 28 62. opportunity
- 29
- 30 63. organisational change theory
- 31
- 32 64. organizational change theory
- 33
- 34 65. personality theory
- 35
- 36 66. precaution adoption process
- 37
- 38 67. protection motivation theory
- 39
- 40 68. reasoned action approach
- 41
- 42 69. reasoned-action approach
- 43
- 44 70. reciprocal causality
- 45
- 46 71. reciprocal determinism
- 47
- 48 72. risk behavior theory
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- 50 73. risk behaviour theory
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- 52 74. self regulation theory
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- 4 75. self determination theory
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- 6 76. self-efficacy theory
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- 8 77. self-perception theory
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- 10 78. self-regulation theory
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- 12 79. social capital
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- 15 80. social change
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- 17 81. social changes
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- 19
- 20 82. social cognition model
- 21
- 22 83. social cognitive theory
- 23
- 24 84. social comparison theory
- 25
- 26 85. social determinism
- 27
- 28 86. social development
- 29
- 30 87. social developments
- 31
- 32 88. social influence
- 33
- 34 89. social learning theories
- 35
- 36 90. social learning theory
- 37
- 38 91. social marketing theory
- 39
- 40 92. social structural theory
- 41
- 42 93. social support
- 43
- 44 94. stage model
- 45
- 46 95. stage of change model
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- 48 96. stages of change model
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- 50 97. systems theory
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- 52 98. theories of planned behaviour
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- 54 99. theories of planned behaviour
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- 100. theory of planned behaviour
- 101. theory of planned behaviour
- 102. theory of reasoned action
- 103. transtheoretical model
- 104. value-expectancy theory

For peer review only