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Sexual well-being among older adults in China (SWELL): protocol for a multicenter observational study

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| Keywords: | SEXUAL MEDICINE, EPIDEMIOLOGY, HIV & AIDS < INFECTIOUS DISEASES, Public health < INFECTIOUS DISEASES |
Sexual well-being among older adults in China (SWELL): protocol for a multicenter observational study

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Abstract

Introduction: Existing studies on sexual health generally focus on younger populations, while the sexual well-being of older adults has received insufficient attention. This protocol describes the design of a study on sexual well-being and its correlates among older adults in China.

Methods and analysis: We present the protocol for a multi-center observational study to investigate sexual well-being among Chinese older adults (SWELL). Eligible participants are men and women aged 50 years and older from East, West, South, and North China, including older adults living in the community and older adults living with HIV (OALHIV). A multi-stage sampling approach is used in the SWELL Study. We will collect a questionnaire about sexual health (sexual knowledge, sexual attitude, sexual behaviors, sexually transmitted infections, etc.). Blood specimens will be tested for sex hormones (estradiol for females, testosterone for males), biochemical items (e.g. cholesterol, triglycerides, low-density lipoprotein, high-density lipoprotein, urea, creatinine, and uric acid), and syphilis [determined by toluidine red unheated serum test (TRUST) and treponema pallidum particle agglutination test (TPPA)]. The primary analysis will elucidate the current status of sexual health among older adults in China and its correlates. Secondary analyses will compare sexual well-being among older adults in four regions across China. Approximately 3540 older adults will be recruited into the SWELL Study.
Ethics and dissemination: This study was approved by the Human Research Ethics Committee of the School of Public Health (Shenzhen), Sun Yat-sen University (approval number SYSU-PHS[2019]006). Verbal informed consent will be obtained from all participants before any study procedure. Data will be anonymized, and participants will not be identified through any data, transcripts, or publications.

Findings from the SWELL Study will be disseminated widely through peer-reviewed scientific journals and at national and international conferences.

Keywords: Sexual health, older adults, sexually transmitted diseases, multi-center observational study; China
Strengths and limitations of this study

- The SWELL Study is the first study to collect, analyze, and synthesize clinical data about sexual well-being among older adults from multiple regions in China.
- This pioneering study will contribute to knowledge building and service planning about sexual well-being among older adults, at local and national levels.
- This research protocol may serve as a valuable guide for other researchers interested in replicating the outlined cross-sectional methodology in order to understand the sexual health status better among older adults.
- The study will be conducted in four regions across China, which are geographically disparate but may not be representative of China as a whole.
Introduction

Sexual health is an indispensable part of holistic health for human, including older adults aged 50 years and older. Epidemiological studies have shown that sexual activity plays an important role among older adults [1–3]. As is discovered in these studies, healthy and enjoyable sexuality could improve multiple aspects of health [3,4], such as protecting mental health [5] and cognitive function [6,7], reducing the risk of cardiovascular disease [8], and reducing all-cause mortality [9]. The health benefits of sex may be more prominent among older adults compared to those who are younger [3]. Compared with sexually inactive peers, sexually active older adults have better functional status and moods [10].

China is striding towards an aging society. By 2050, the older adults will account for 26.1% of the country's total population [11]. The increasingly aging population poses significant challenges to the healthcare system. Many older adults remain sexually active, and a subset may be at risk of sexually transmitted diseases [10,12]. At the same time, immunosenescence (i.e. decreased immune function due to aging) makes older adults more vulnerable to infections, including sexually transmitted infections (STIs) [13]. The incidence of STIs in older adults is rising, making it a formidable public health challenge [14,15]. Much of the understanding of factors that explain variation in sexual health among older adults is mainly based on data from developed regions. There is limited research that has assessed sexual health and its influence factors among Chinese older adults.
The sexual well-being among older adults in China (SWELL) study is a multicentric observational study aimed at elucidating the current status of sexual health among older adults aged 50 years and older in China and its correlates.

The main research questions of the SWELL Study include three aspects:

1. Sexual behaviors among older adults.
2. Sexual health and its correlates among older adults.

This protocol details the survey instrument, the multistage recruitment strategy, the study procedures, and risk mitigation protocols for different participants. It represents a significant methodological resource for researchers exploring sexual health status among older adults, and serves as a valuable guide for those interested in replicating the outlined cross-sectional methodology to better understand sexual health among older adults.

**Methods and analysis**

**Study design and setting**

SWELL is a multicenter cross-sectional study. We will investigate the current status of sexual health and its correlates among older adults aged 50 years and older, including older adults living in the community and older adults living with HIV (OALHIV).

**Ethical considerations**

During the planning phase, meetings for stakeholders are held to discuss the feasibility of the SWELL Study. Investigators and study personnel are trained about research
ethics and human subjects protection. All procedures contributing to this work comply with the ethical standards of relevant national and institutional committees on human experimentation and with the Helsinki Declaration. Verbal informed consent will be obtained from all participants before any study procedure. This study (including verbal informed consent) was approved by the Human Research Ethics Committee of the School of Public Health (Shenzhen), Sun Yat-sen University (approval number SYSU-PHS[2019]006) (Appendix 1). Data will be anonymized, and participants will not be identified through any data, transcripts, or publications. Findings from the SWELL Study will be disseminated widely through peer-reviewed scientific journals and at national and international conferences.

**Patient and public involvement**

Patients and/or the public were not involved in the design, conduct, reporting, or dissemination plans of this research.

**Study population**

**Sample size**

The sample size is calculated based on the rate of sexual dysfunction. According to a study about sexual problems among Chinese older adults [16], we used 20% and 32% as the rate of sexual dysfunction in males and females, which are denoted by $P$ in the following formula:

$$N = \frac{z_{\alpha}^2 \cdot P \cdot (1 - P)}{d^2}$$

$z_{\alpha}$: $Z$-statistic
Based on these assumed parameters, we aim to recruit 1600 men and 850 women. To ensure sufficient power to allow for subgroup analyses, we will recruit 20% extra participants in each group. We will recruit OALHIV to understand their current sexual health status. According to existing literatures about sexual behaviors among OALHIV [17], we used 33% for the prevalence of sexual activeness (i.e. having sexual activity in the past 12 months) as $P$ in the formula. 600 older adults living with HIV will be recruited to the SWELL Study. A total of 3540 older adults will be recruited into the SWELL Study.

**Sampling method**

Multi-stage sampling will be used in the SWELL Study. The following section outlines a general approach to the sampling process, except for slight variations between institutions based on site-specific regulations and preferences for data management. One province in each of the four regions will be randomly selected: East, West, South, and North China. The capital city of each selected province is our study site. For community sample, eligible men and women will be recruited at subdistricts. Subdistricts (i.e. streets and avenues, are a form of township-level division which is typically part of a larger urban area, as opposed to a discrete town surrounded by rural areas, or a rural township) in each city are assigned a five-digit alphanumeric identification (ID) number. Before initiation of the study, a dataset called ‘selection
pool' is created. All subdistrict IDs are included in the dataset. Four independent
subdistrict IDs are randomly drawn in each selected city to determine four survey sites
by the software SAS 9.4. A total of 16 survey sites are finally selected. The multi-stage
sampling frame is shown in Figure 1. At each survey site, the stratifying variables - age
and gender - are used to ensure the representativeness of the sample. The files returned
to the research team did not contain any personal information. Separately, older adults
living with HIV will be recruited at one designated hospital in each of the selected cities.

Eligibility criteria

Each participant should meet the following eligibility criteria:

· aged ≥50 years
· have ever had oral, or vaginal, or anal sex
· understand the survey instrument of the SWELL Study
· HIV diagnosis history (for OALHIV)

Survey instrument

The survey instrument used in SWELL Study is adapted from the UK Nastal-3 survey
instrument [18]. Variables including sociodemographic characteristics, general health
status, sexual lifestyles characteristics (e.g. sexual experience, sexual behaviors, quality
of sexual life, and attitude toward sex), and sexual health status (e.g. sex education,
sexually transmitted infections, sexual health service needs) will be collected. We
localized the questionnaire through several pre-surveys. The comparison between items
included in Natsal-3 and SWELL is shown in Table 1.
Table 1. The survey instruments content of Natsal-3 and SWELL Study

<table>
<thead>
<tr>
<th>Survey instruments content</th>
<th>Natsal-3</th>
<th>SWELL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Socio-demographics</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>General health, health conditions, medications taken, medical procedures</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Childhood experiences</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Learning about sex</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Attitudes towards different types of relationship</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>First heterosexual experience</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Contraception use</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Periods, menopause and use of hormone replacement therapy</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Experience of different heterosexual practices (vaginal, oral and anal intercourse)</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Opposite-sex sex in the last 4 weeks and condom use</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Same-sex sexual experiences (types of sexual practices, sex in last 4 weeks)</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Number of opposite-sex partners in different time periods (lifetime, 5 years, 1 year, 3 months)</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Number of same-sex partners in different time periods</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Details of most recent partners</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Overseas sexual experiences and sex with foreigners</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Non-volitional sex</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Paying for sex</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Family formation, pregnancy history and unplanned pregnancy</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Fertility intentions and infertility</td>
<td>✓</td>
<td>×</td>
</tr>
<tr>
<td>STI diagnosis and treatment, HPV vaccination and cervical cancer screening*</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Circumcision</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>HIV testing</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Sexual function and satisfaction</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Use of Viagra</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Use of recreational drugs</td>
<td>✓</td>
<td>×</td>
</tr>
<tr>
<td>Depressive symptoms</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Study procedures

The study procedures are shown in Figure 2.

Investigator recruitment and training
To build a stable investigation team, local medical staff/social workers will be recruited as investigators for the SWELL Study. To ensure the quality of investigation, all investigator candidates will be required to go through standard training and pass a 20-minute qualification test.

**Informed consent**

Participants are recruited by local centers for disease control and prevention (CDCs) or non-governmental organizations. An informed consent will be obtained before any study procedure. Each potential participant will receive a set of unique eight-digit barcodes (including three identical barcodes) that matches survey data with the biological specimen. The function of barcodes during the investigation process is shown in Appendix 2.

**Survey phase**

Due to the uneven reading ability of the older adults, for a better quality of the survey data, investigators will interview older adults one-on-one in a quiet and confidential space. Participants may self-complete the questionnaire if they choose to. Participants will then submit one of the barcodes to the investigators to fill their study ID in the survey instrument.

**Specimen sampling phase**

After the survey phase, the participant will be brought to another room where the blood specimen is taken. The remaining two barcodes will be handed to the staff. One is used
to label the blood collection tube, and the other is registered as a blood collection record.

A trained nurse will collect 5 mL of blood for laboratory testing.

The great majority of PLHIV undergo regular physical examinations and tests for syphilis. Their clinical data together with laboratory testing results can be linked to our study dataset, within which only a urine sample will be collected to test for chlamydia.

In the end, each participant will be offered a gift card which is worth CNY 50 (USD 7.5). Each specimen will be labeled with a unique ID number that matches the participant’s laboratory requisition form, testing results form, as well as the study dataset. No identifiable personal information will be included in any specimen label or laboratory form.

**Specimen testing phase**

A blood sample will be taken, stored at a low temperature (4 °C), and transported to the certified laboratory within 24 hours. Blood specimens will be tested for sex hormones, biochemical items, and syphilis status. Sex hormones (estradiol for females, testosterone for males) will be assayed by direct chemiluminescence using acridinium ester technology. Biochemical items including blood lipid (cholesterol, triglycerides, low-density lipoprotein, and high-density) and kidney function (urea, creatinine and uric acid) will be analyzed using Combas C702 automatic chemical analyzer. The syphilis status will be determined by toluidine red unheated serum tests (TRUST) and Treponema pallidum particle agglutination (TPPA) tests. Laboratory personnel can
only see the barcode of each participant during the specimen testing process, so the personal information of participants can be protected.

For older adults living with HIV, the following clinical data will be retrieved from medical records: HIV-related medical history and laboratory testing results (e.g. time since HIV diagnosis, duration on ART, viral load, etc.) and diagnosis of comorbidities (e.g. arthritis, heart attack, coronary heart disease, angina, other forms of heart disease, hyperuricemia, hypertension, stroke, diabetes, any other muscle or bone disease lasting longer than 3 months, and chronic airways disease.).

Risk mitigation protocols

Researchers will examine the survey data and testing results separately during the risk management process. Risk management method is from one of four pre-specified protocols developed by the research team in collaboration with a local participating CDC. Mitigation protocols are programmed hierarchically, which means they are numbered in ascending order of priority. The summary of each protocol is provided below.

Protocol 1: Protocol for participants who are tested positive for syphilis

A positive syphilis diagnosis is defined as a positive result for either TPPA or TRUST. The eight-digit barcode of a participant with a positive syphilis diagnosis will be recorded, and sent to the participating CDC. As a fail-safe mechanism, the three primary investigators of the project will receive an email notifying them that Protocol 1 has been triggered. The medical staff of the CDC will reach out to the participant
within one business day of receiving feedback and offer them a re-examination appointment at a designated hospital within one week. The final data is subject to the re-examination result. Participants diagnosed with syphilis will be treated in designated hospitals.


The eight-digit barcode of a participant with cardiovascular diseases will be recorded. The medical workers of the CDC will reach out to the participant within one business day and give feedback to the affiliated subdistrict hospital of the city where the investigation site is located. The medical staff of the subdistrict hospital will check with the current chronic disease management list. If the participant is not on the list, the medical staff of the subdistrict hospital will include the participant in the chronic disease daily management system after getting in touch with him/her.

Protocol 3: Protocol for participants with abnormal body mass index.

Older adults' body mass index is considered to be abnormal when it is lower than 18.5 or higher than 24 in the SWELL Study. Participants with an underweight or overweight body mass index will receive a recommended guideline upon survey completion that provides information on exercise advice and diet management.

Protocol 4: Standard general protocol.

As a standard general precaution, all participants who did not trigger a specific protocol will receive a brochure upon survey completion that provides tips for healthy aging and recommendations about a healthy lifestyle.
Data security & data management

Data download

The data will be exported from the digital platform in .CSV format upon study closure. As the study closes each week, the .CSV files will be uploaded weekly to a secure institutional storage platform. As per the Data Security Protocols, only members of the steering committee will have access to the data (see below).

Data security protocols

The primary tenet for data security is that all data access is need-to-know. This rule is reflected in all facets of data management in the study administration process. All data relating to the project, including survey data and laboratory-testing data, are stored on a secure file storage platform. To ensure that all data are handled securely, stringent processes need to be followed when accessing, storing, and downloading data as per institutional guidelines. Since the data involve sensitive privacy, such as sexual experiences and behaviors, it is vital to uphold a high level of anonymity. The survey is anonymous.

Statistical analysis

The general statistical analysis will be carried out using standard and professional statistical software, such as SPSS (v24.0 for macOS), and SAS (v9.4 for macOS). Simple descriptive statistics will be used to describe the distributions of variables. Meanwhile, multiple model fitting and comparison will be conducted to select the best
model to explore the current sexual health status and influencing factors among older adults in China.

**Discussion**

Accurate information about a nation’s sexual health is essential to the planning and evaluation of services, informing prevention efforts, and contributing to the societal discourse on sexuality. Studies on sexual behaviors have come a long way since the pioneering but methodologically problematic studies carried out by Kinsey in the USA in 1948 [19]. The emergence of the HIV/AIDS epidemic in the 1980s provided the imperative for collecting reliable data on sexual behaviors, as epidemiologists and public health specialists recognized that the implementation science for solving sexual health problems needs data support and theoretical basis [19].

In an aging society, it is critical to understand the sexual health needs of older adults. The vision of the SWELL Study is provide reference for future policy on sexual healthcare, by collecting and analyzing data from a multi-center survey about sexual health of older adults in China. As the pioneering survey on sexual health among older adults which collects data from multiple regions, the SWELL Study may contribute to knowledge building and service planning at both a local and national level. The data will provide a comprehensive and comparative picture of current sexual health among older adults in China. We anticipate the SWELL Study to generate high-quality evidence to inform sexual health strategies for Chinese older adults.
As an innovative study about sexual health among Chinese older adults, the SWELL Study may be susceptible to challenges arising from conservative stereotypes about sexual health. We hope to ease these challenges by standardizing and testing operating procedures in advance, periodic study monitoring, evaluation processes, and interdisciplinary cooperation in public health, implementation science, and social sciences, ensuring stakeholder involvement and support at all stages of the study. The protocol of the SWELL Study incorporates a multi-tiered recruitment strategy and comprehensive risk mitigation procedures. It could extend current literature to find a solution for complex problems about sexual health among Chinese older adults. Furthermore, standardized protocol, data collection, and operating procedures will ensure high-quality data. Consistent with a holistic geriatrics approach, sexual health issues cannot be addressed alone. The experts from multidisciplinary domains in SWELL Study, including Public Health, Clinical Medicine, Social Medicine, Health Service Management, Epidemiology, and Health Statistics, will provide optimal study oversight. We believe the findings of the SWELL Study will guide practice decisions on sexual health promotion among older adults in China. The results will also contribute to comprehensive and evidence-based recommendations on policies, practices, and strategies to promote sexual health among older adults. This research protocol may serve as a valuable guide for other researchers interested in replicating the outlined cross-sectional methodology in order to understand the sexual health status better.
among older adults.

**Abbreviations**

- SWELL: Sexual well-being among older adults in China
- OALHIV: Older adults living with HIV
- STIs: sexually transmitted infections
- HIV: Human immunodeficiency virus
- CDC: Center for Disease Control and Prevention
- ID: Identification
- Natsal: British National Surveys of Sexual Attitudes and Lifestyles

**Figure legends**

- Figure 1. The multi-stage sampling framework of SWELL study
- Figure 2. The study procedures of SWELL study

**Supplementary information**

- Appendix 1. Human Research Ethics Committee of the School of Public Health
  (Shenzhen), Sun Yat-sen University approval document
- Appendix 2. The function of barcodes during the investigation procedures

**Declarations**

**Ethics approval and consent to participate**

All procedures contributing to this work comply with the ethical standards of relevant national and institutional committees on human experimentation and with the Helsinki Declaration. Verbal informed consent will be obtained from all participants before any
procedure of the SWELL Study. The SWELL Study (including verbal informed consent) was approved by the Human Research Ethics Committee of the School of Public Health (Shenzhen), Sun Yat-sen University (approval number SYSU-PHS[2019]006).

Consent to publish

Not applicable.

Availability of data and materials

The data collected in this study will not be publicly available. However, the corresponding author can be contacted for de-identified data upon reasonable request.

Competing interests statement

The authors declare that they have no competing interests.

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**Authors’ contributions**

HZ conceived the study. BW, XP, BL, LF, TS, and TT drafted the protocol. XL, XX, GW, LO, MY, YC, YW, XM, JT, DW, WT, and HZ revised the manuscript. All authors have read and approved the final manuscript.

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BW, XP, BL, LF, and TT contributed equally to this work.

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REFERENCE


Investigators recruitment

Training & Examination

Qualification certificate

Participants recruitment

Informed consent

Survey phase

Specimen sampling phase

Specimen testing phase

Survey data

- Age ≥50 years
- Have ever had any sexual activities
- Understand the questionnaire
- Agree to provide a blood sample

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BMJ Open
公共卫生学院（深圳）医学伦理委员会审批件

<table>
<thead>
<tr>
<th>编号：中大公卫（深圳）医伦（2019）第006号</th>
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</thead>
<tbody>
<tr>
<td><strong>研究项目名称</strong></td>
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</table>
| **研究内容及意义** | 医学技术的发展及寿命的延长，使得老年人群可能在很长一段时间内仍然保持持续活跃的性生活，而身体机能的衰老带来的影响性健康状况的问题日渐凸显。

本研究旨在通过参与性社区驱动方法，借助多学科跨地区合作的方式调查中英两国老龄人口性健康状况，通过比较双方差异，寻找双方遇到的难点，并通过离散选择实验（DCE）及众包竞赛的方式寻找改善两国性健康服务的途径，为改善中英两国老龄人口性健康服务提供政策建议。 |
| **项目负责人** | 邹华春 |
| **项目类别** | 国家自然科学基金委员会与英国经济与社会研究理事会、英国医学研究理事会跨学科研究项目 |
| **研究年限** | 2020 年 5 月 1 日至 2023 年 4 月 30 日 |

医学伦理委员会审批意见：
同意该项目在获得研究对象知情同意的情况下开展

[公章]

中山大学公共卫生学院（深圳）
生物医学研究伦理审查委员会

主任委员：

公共卫生学院（深圳）
生物医学研究伦理审查委员会

2023年6月30日

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Barcode 1
For survey instrument

Barcode 2
For specimen sampling

Barcode 3
For specimen testing

Survey instrument
Specimen
Test report confirmation form
<table>
<thead>
<tr>
<th>Item No</th>
<th>Recommendation</th>
<th>Page No</th>
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<tbody>
<tr>
<td>1.1</td>
<td>(a) Indicate the study’s design with a commonly used term in the title or the abstract</td>
<td>1</td>
</tr>
<tr>
<td>1.2</td>
<td>(b) Provide in the abstract an informative and balanced summary of what was done and what was found</td>
<td>4-5</td>
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<tr>
<td>2</td>
<td>Explain the scientific background and rationale for the investigation being reported</td>
<td>7</td>
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<td>3</td>
<td>State specific objectives, including any prespecified hypotheses</td>
<td>8</td>
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<td>4</td>
<td>Present key elements of study design early in the paper</td>
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<td>5</td>
<td>Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection</td>
<td>8</td>
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<tr>
<td>6.1</td>
<td>(a) Give the eligibility criteria, and the sources and methods of selection of participants</td>
<td>10-11</td>
</tr>
<tr>
<td>6.2</td>
<td>(b) Give the sources and methods of selection of participants</td>
<td>10-11</td>
</tr>
<tr>
<td>7</td>
<td>Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable</td>
<td>11-12</td>
</tr>
<tr>
<td>8*</td>
<td>For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group</td>
<td>11-12</td>
</tr>
<tr>
<td>9</td>
<td>Describe any efforts to address potential sources of bias</td>
<td>10-11</td>
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<td>10</td>
<td>Explain how the study size was arrived at</td>
<td>9-10</td>
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<td>11</td>
<td>Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why</td>
<td>N/A</td>
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<tr>
<td>12</td>
<td>(a) Describe all statistical methods, including those used to control for confounding</td>
<td>17</td>
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<td>13</td>
<td>(b) Describe any methods used to examine subgroups and interactions</td>
<td>17</td>
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<tr>
<td>14</td>
<td>(c) Explain how missing data were addressed</td>
<td>18</td>
</tr>
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<td>15</td>
<td>(d) If applicable, describe analytical methods taking account of sampling strategy</td>
<td>18</td>
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<tr>
<td>16</td>
<td>(e) Describe any sensitivity analyses</td>
<td>18</td>
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<tr>
<td>13*</td>
<td>(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed</td>
<td>N/A</td>
</tr>
<tr>
<td>14*</td>
<td>(b) Give reasons for non-participation at each stage</td>
<td>N/A</td>
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<tr>
<td>15*</td>
<td>(c) Consider use of a flow diagram</td>
<td>N/A</td>
</tr>
<tr>
<td>16</td>
<td>(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders</td>
<td>N/A</td>
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<tr>
<td>17</td>
<td>(b) Indicate number of participants with missing data for each variable of interest</td>
<td>N/A</td>
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<tr>
<td>18</td>
<td>Report numbers of outcome events or summary measures</td>
<td>N/A</td>
</tr>
<tr>
<td>19</td>
<td>(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included</td>
<td>N/A</td>
</tr>
</tbody>
</table>
(b) Report category boundaries when continuous variables were categorized

(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period

<table>
<thead>
<tr>
<th>Other analyses</th>
<th>Report other analyses done—e.g. analyses of subgroups and interactions, and sensitivity analyses</th>
<th>N/A</th>
</tr>
</thead>
</table>

**Discussion**

<table>
<thead>
<tr>
<th>Key results</th>
<th>Summarise key results with reference to study objectives</th>
<th>18</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limitations</td>
<td>Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias</td>
<td>18-19</td>
</tr>
<tr>
<td>Interpretation</td>
<td>Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence</td>
<td>18-19</td>
</tr>
<tr>
<td>Generalisability</td>
<td>Discuss the generalisability (external validity) of the study results</td>
<td>18-19</td>
</tr>
</tbody>
</table>

**Other information**

| Funding | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | 21 |

*Give information separately for exposed and unexposed groups.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.
Sexual well-being among older adults in China (SWELL): protocol for a multicenter cross-sectional study

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Primary Subject Heading: Public health
Sexual well-being among older adults in China (SWELL): protocol for a multicenter cross-sectional study

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Word count: 2660
Abstract

Introduction: Existing studies on sexual health generally focus on younger populations, while the sexual well-being of older adults has received insufficient attention. This protocol describes the design of a study on sexual well-being and its correlates among older adults in China.

Methods and analysis: We present the protocol for a multi-center observational study to investigate sexual well-being among Chinese older adults (SWELL). Eligible participants are men and women aged 50 years and older from East, West, South, and North China, including older adults living in the community and older adults living with HIV (OALHIV). A multi-stage sampling approach is used in the SWELL Study. We will collect a questionnaire about sexual health (sexual knowledge, sexual attitude, sexual behaviors, sexually transmitted infections, etc.). Blood specimens will be tested for sex hormones (estradiol for females, testosterone for males), biochemical items (e.g. cholesterol, triglycerides, low-density lipoprotein, high-density lipoprotein, urea, creatinine, and uric acid), and syphilis [determined by toluidine red unheated serum test (TRUST) and treponema pallidum particle agglutination test (TPPA)]. The primary analysis will elucidate the current status of sexual health among older adults in China and its correlates. Secondary analyses will compare sexual well-being among older adults in four regions across China. Approximately 3540 older adults will be recruited into the SWELL Study.
Ethics and dissemination: This study was approved by the Human Research Ethics Committee of the School of Public Health (Shenzhen), Sun Yat-sen University (approval number SYSU-PHS[2019]006). Verbal informed consent will be obtained from all participants before any study procedure. Data will be anonymized, and participants will not be identified through any data, transcripts, or publications. Findings from the SWELL Study will be disseminated widely through peer-reviewed scientific journals and at national and international conferences.

Keywords: Sexual health, older adults, sexually transmitted diseases, multi-center observational study; China
Strengths and limitations of this study

- The SWELL Study is the first study to collect, analyze, and synthesize clinical data about sexual well-being among older adults from multiple regions in China.
- This pioneering study will contribute to knowledge building and service planning about sexual well-being among older adults, at local and national levels.
- This research protocol may serve as a valuable guide for other researchers interested in replicating the outlined cross-sectional methodology in order to understand the sexual health status better among older adults.
- The study will be conducted in four regions across China, which are geographically disparate but may not be representative of China as a whole.
Introduction

Sexual health is an indispensable part of holistic health for human, including older adults aged 50 years and older. Epidemiological studies have shown that sexual activity plays an important role among older adults [1–3]. As is discovered in these studies, healthy and enjoyable sexuality could improve multiple aspects of health [3,4], such as protecting mental health [5] and cognitive function [6,7], reducing the risk of cardiovascular disease [8], and reducing all-cause mortality [9]. The health benefits of sex may be more prominent among older adults compared to those who are younger [3]. Compared with sexually inactive peers, sexually active older adults have better functional status and moods [10].

China is striding towards an aging society. By 2050, the older adults will account for 26.1% of the country’s total population [11]. The increasingly aging population poses significant challenges to the healthcare system. Many older adults remain sexually active, and a subset may be at risk of sexually transmitted diseases [10,12]. At the same time, immunosenescence (i.e. decreased immune function due to aging) makes older adults more vulnerable to infections, including sexually transmitted infections (STIs) [13]. The incidence of STIs in older adults is rising, making it a formidable public health challenge [14,15]. Much of the understanding of factors that explain variation in sexual health among older adults is mainly based on data from developed countries. There is limited research that has assessed sexual health and its influence factors among Chinese older adults.
The sexual well-being among older adults in China (SWELL) study is a multicentric observational study aimed at elucidating the current status of sexual health among older adults aged 50 years and older in China and its correlates.

The main research questions of the SWELL Study include three aspects:

1. What are sexual lifestyles among older adults, such as sexual experience, sexual behaviors, quality of sexual life, sexual needs, and attitude toward sex?
2. What are the correlates of sexual health among older adults?
3. How to improve sexual health among older adults?
4. What are the sexual health services that older adults prefer?

This protocol details the survey instrument, the multistage recruitment strategy, the study procedures, and risk mitigation protocols for different participants. It represents a significant methodological resource for researchers exploring sexual health status among older adults, and serves as a valuable guide for those interested in replicating the outlined cross-sectional methodology to better understand sexual health among older adults.

Methods and analysis

Study design and setting

SWELL is a multicenter cross-sectional study. We will investigate the current status of sexual health and its correlates among older adults aged 50 years and older, including older adults living in the community and older adults living with HIV (OALHIV). The planned start and end dates for this study are June 2021 and June 2023, respectively.
**Ethical considerations**

During the planning phase, meetings for stakeholders (including older adults in the community, older adults living with HIV, healthcare providers, social workers, and research administrators from SWELL Study) are held to discuss the feasibility of the SWELL Study. Investigators and study personnel received training on research ethics and human subjects protection. All procedures contributing to this work comply with the ethical standards of relevant national and institutional committees on human experimentation and with the Helsinki Declaration. Verbal informed consent will be obtained from all participants before any study procedure. This study (including verbal informed consent) was approved by the Human Research Ethics Committee of the School of Public Health (Shenzhen), Sun Yat-sen University (approval number SYSU-PHS[2019]006) (Appendix 1). Data will be anonymized, and participants will not be identified through any data, transcripts, or publications. Findings from the SWELL Study will be disseminated widely through peer-reviewed scientific journals and at national and international conferences.

**Patient and public involvement**

Patients and/or the public were not involved in the design, conduct, reporting, or dissemination plans of this research.

**Study population**

**Sample size**
The sample size is calculated based on the rate of sexual dysfunction. According to a study about sexual problems among Chinese older adults [16], we used 20% and 32% as the rate of sexual dysfunction in males and females, which are denoted by $P$ in the following formula:

$$N = \frac{z_a^2 \cdot P \cdot (1 - P)}{d^2}$$

$z_a$: Z-statistic

$P$: Feature prevalence

$d$: Accuracy level

Based on these assumed parameters, we aim to recruit 1600 males and 850 females. To ensure sufficient power to allow for subgroup analyses, we will recruit 20% extra participants in each group. We will recruit OALHIV to understand their current sexual health status. According to existing literatures about sexual behaviors among OALHIV [17], we used 33% for the prevalence of sexual activeness (i.e. having sexual activity in the past 12 months) as $P$ in the formula. 600 OALHIV (400 males and 200 females) will be recruited to the SWELL Study. A total of 3540 older adults will be recruited into the SWELL Study.

**Sampling method**

Multi-stage sampling will be used in the SWELL Study. The following section outlines a general approach to the sampling process, except for slight variations between institutions based on site-specific regulations and preferences for data management.

One province in each of the four regions will be randomly selected: East, West, South,
and North China. The capital city of each selected province is our study site. For community sample, eligible males and females will be recruited at subdistricts. Subdistricts (i.e. streets and avenues, are a form of township-level division which is typically part of a larger urban area, as opposed to a discrete town surrounded by rural areas, or a rural township) in each city are assigned a five-digit alphanumeric identification (ID) number. Before initiation of the study, a dataset called ‘selection pool’ is created. All subdistrict IDs are included in the dataset. Four independent subdistrict IDs are randomly drawn in each selected city to determine four survey sites by the software SAS 9.4. A total of 16 survey sites are finally selected. The multi-stage sampling frame is shown in Figure 1. At each survey site, the stratifying variables - age and gender - are used to ensure the representativeness of the sample. The files returned to the research team did not contain any personal information. Separately, OALHIV will be recruited at one designated hospital in each of the selected cities.

**Eligibility criteria**

Each participant should meet the following eligibility criteria:

- aged ≥50 years
- have ever had oral, or vaginal, or anal sex
- understand the survey instrument of the SWELL Study
- HIV diagnosis history (for OALHIV)

**Survey instrument**
The survey instrument used in SWELL Study is adapted from the UK Nastal-3 survey instrument [18]. Multi-domain variables will be collected, including sociodemographic characteristics (e.g. gender, age, relationship status, monthly income, education levels, and employment status), general health status, sexual lifestyles characteristics (e.g. sexual experience, sexual behaviors, quality of sexual life, sexual needs and attitude toward sex), and sexual health indicators (e.g. sex education levels, previous sexually transmitted infections, sexual health service needs). Different from Natsal-3, which is based on the whole population (aged 16-74 years), SWELL Study focuses on older adults. Therefore, we have adjusted the content of the survey instrument. The comparison between items included in Natsal-3 and SWELL is shown in Table 1.

Before the survey was launched formally, we localized the survey instrument through a small-sample pre-survey (pilot study).

Sexual lifestyles characteristics were the most significant outcome variables. In the SWELL Study, older adults who reported recent sexual activity (including vaginal, oral, or anal sex) in the past years were categorized as sexually active. Sexual function was assessed by the Natsal-SF and the lowest quintile of the gender-specific population score distribution was considered low sexual function, as defined by previous studies [19].

Table 1. The survey instruments content of Natsal-3 and SWELL Study

<table>
<thead>
<tr>
<th>Survey instruments content</th>
<th>Natsal-3</th>
<th>SWELL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Socio-demographics</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>General health, health conditions, medications taken, medical procedures</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>
Childhood experiences
Learning about sex
Attitudes towards different types of relationship
First heterosexual experience
Contraception use
Periods, menopause and use of hormone replacement therapy
Experience of different heterosexual practices (vaginal, oral and anal intercourse)
Opposite-sex sex in the last 4 weeks and condom use
Same-sex sexual experiences (types of sexual practices, sex in last 4 weeks)
Number of opposite-sex partners in different time periods (lifetime, 5 years, 1 year, 3 months)
Number of same-sex partners in different time periods
Details of most recent partners
Overseas sexual experiences and sex with foreigners
Non-volitional sex
Paying for sex
Family formation, pregnancy history and unplanned pregnancy†
Fertility intentions and infertility‡
STIs diagnosis and treatment, HPV vaccination and cervical cancer screening*
Circumcision
HIV testing
Sexual function and satisfaction
Use of Viagra
Use of recreational drugs§
Depressive symptoms

†Questions related to unplanned pregnancy were not applicable.
‡Not applicable to the study population.
*Questions related to the HPV vaccination were not applicable. HBV and HCV infection status were included in this part.
§The pre-survey showed that the prevalence was too low and was therefore excluded.

Study procedures

The study procedures are shown in Figure 2.

Investigator recruitment and training
To build a stable investigation team, local medical staff/social workers will be recruited as investigators for the SWELL Study. To ensure the quality of investigation, all investigator candidates will be required to go through standard training and pass a 20-minute qualification test.

Informed consent

Participants are recruited by local centers for disease control and prevention (CDCs) or non-governmental organizations. An informed consent will be obtained before any study procedure. Each potential participant will receive a set of unique eight-digit barcodes (including three identical barcodes) that matches survey data with the biological specimen. The function of barcodes during the investigation process is shown in Appendix 2.

Survey phase

Due to the uneven reading ability of the older adults, for a better quality of the survey data, investigators will interview older adults one-on-one in a quiet and confidential space. Participants may self-complete the questionnaire if they choose to. Participants will then submit one of the barcodes to the investigators to fill their study ID in the survey instrument.

Specimen sampling phase

After the survey phase, the participant will be brought to another room where the blood specimen is taken. The remaining two barcodes will be handed to the staff. One is used
to label the blood collection tube, and the other is registered as a blood collection record.

A trained nurse will collect 5 mL of blood for laboratory testing.

The great majority of PLHIV undergo regular physical examinations and tests for syphilis. Their clinical data together with laboratory testing results can be linked to our study dataset, within which only a urine sample will be collected to test for chlamydia.

In the end, each participant will be offered a gift card worth CNY 50 (USD 7.5). Each specimen will be labeled with a unique ID number that matches the participant’s laboratory requisition form, testing results form, and the study dataset. No identifiable personal information will be included in any specimen label or laboratory form.

**Specimen testing phase**

A blood sample will be taken, stored at a low temperature (4 °C), and transported to the certified laboratory within 24 hours. Blood specimens will be tested for sex hormones, biochemical items, and syphilis status. Sex hormones (estradiol for females, testosterone for males) will be assayed by direct chemiluminescence using acridinium ester technology. Biochemical items including blood lipid (cholesterol, triglycerides, low-density lipoprotein, and high-density) and kidney function (urea, creatinine and uric acid) will be analyzed using Combas C702 automatic chemical analyzer. The syphilis status will be determined by toluidine red unheated serum tests (TRUST) and Treponema pallidum particle agglutination (TPPA) tests. Laboratory personnel can only see the barcode of each participant during the specimen testing process, so the personal information of participants can be protected. HIV-1 Western Blot Bio-Rad
assay (Bio-Rad Laboratories, Redmond, WA, USA) was used to confirm positive
samples.

For OALHIV, the following clinical data will be retrieved from medical records: HIV-
related medical history and laboratory testing results (e.g. time since HIV diagnosis,
duration on ART, viral load, etc.), diagnosis of comorbidities (e.g. arthritis, heart attack,
coronary heart disease, angina, other forms of heart disease, hyperuricemia,
hypertension, stroke, diabetes, any other muscle or bone disease lasting longer than 3
months, and chronic airways disease.), sexually transmitted infections (e.g. syphilis,
chlamydia, and gonorrhea) and opportunistic infections (e.g. herpes zoster, bacterial
pneumonia, pulmonary and extra-pulmonary tuberculosis, oral and oesophageal
candidiasis, pneumocystis pneumonia, toxoplasmosis, cryptococcal meningitis, non-
Hodgkin’s lymphoma, and Kaposi’s sarcoma).

Risk mitigation protocols

Researchers will examine the survey data and testing results separately during the risk
management process. Risk management method is from one of four pre-specified
protocols developed by the research team in collaboration with a local participating
CDC. Mitigation protocols are programmed hierarchically, which means they are
numbered in ascending order of priority. The summary of each protocol is provided
below.

Protocol 1: Protocol for participants who are tested positive for syphilis

Mitigation protocols are programmed hierarchically, which means they are
numbered in ascending order of priority. The summary of each protocol is provided
below.
A positive syphilis diagnosis is defined as a positive result for either TPPA or TRUST. The eight-digit barcode of a participant with a positive syphilis diagnosis will be recorded, and sent to the participating CDC. As a fail-safe mechanism, the three primary investigators of the project will receive an email notifying them that Protocol 1 has been triggered. The medical staff of the CDC will reach out to the participant within one business day of receiving feedback and offer them a re-examination appointment at a designated hospital within one week. The final data is subject to the re-examination result. Participants diagnosed with syphilis will be treated for syphilis at the first visit to the designated hospital.

Protocol 2: Protocol for participants with cardiovascular diseases. The eight-digit barcode of a participant with cardiovascular diseases will be recorded. The medical workers of the CDC will reach out to the participant within one business day and give feedback to the affiliated subdistrict hospital of the city where the investigation site is located. The medical staff of the subdistrict hospital will check with the current chronic disease management list. If the participant is not on the list, the medical staff of the subdistrict hospital will include the participant in the chronic disease daily management system after getting in touch with him/her.

Protocol 3: Protocol for participants with abnormal body mass index. Older adults' body mass index is considered to be abnormal when it is lower than 18.5 or higher than 24 in the SWELL Study. Participants with an underweight or overweight
body mass index will receive a recommended guideline upon survey completion that provides information on exercise advice and diet management.

Protocol 4: Standard general protocol.

As a standard general precaution, all participants who did not trigger a specific protocol will receive a brochure upon survey completion that provides tips for healthy aging and recommendations about a healthy lifestyle.

Data security & data management

Data download

The data will be exported from the digital platform in .CSV format upon study closure.

As the study closes each week, the .CSV files will be uploaded weekly to a secure institutional storage platform. As per the Data Security Protocols, only members of the steering committee will have access to the data (see below).

Data security protocols

The primary tenet for data security is that all data access is need-to-know. This rule is reflected in all facets of data management in the study administration process. All data relating to the project, including survey data and laboratory-testing data, are stored on a secure file storage platform. To ensure that all data are handled securely, stringent processes need to be followed when accessing, storing, and downloading data as per institutional guidelines. Since the data involve sensitive privacy, such as sexual experiences and behaviors, it is vital to uphold a high level of anonymity. The survey is anonymous.
Statistical analysis

The general statistical analysis will be carried out by standard and professional statistical software, such as SPSS (v24.0 for macOS), and SAS (v9.4 for macOS). The qualitative analysis will be conducted by the qualitative analysis software, including Atlas.ti (v8.0), and NVivo (v12.0). Simple descriptive statistics will be used to describe the distributions of variables. Meanwhile, the associations between independent variables (e.g. sociodemographic characteristics and general health status) and the outcome variables (e.g. sexual lifestyles characteristics and sexual health indicators) will be analyzed by multivariable logistics models. Subgroup analysis will be performed by studying the differences between age, sex (female/male), HIV status (i.e., OALHIV and older adults living in the community), and geographic region (East, West, South, and North China).

Discussion

Accurate information about a nation’s sexual health is essential to the planning and evaluation of services, informing prevention efforts, and contributing to the societal discourse on sexuality. Studies on sexual behaviors have come a long way since the pioneering but methodologically problematic studies carried out by Kinsey in the USA in 1948 [20]. The emergence of the HIV/AIDS epidemic in the 1980s provided the imperative for collecting reliable data on sexual behaviors, as epidemiologists and public health specialists recognized that the implementation science for solving sexual health problems needs data support and theoretical basis [20].
In an aging society, it is critical to understand the sexual health needs of older adults. The vision of the SWELL Study is to provide a reference for future policy on sexual healthcare, by collecting and analyzing data from a multi-center survey about the sexual health of older adults in China. As the pioneering survey on sexual health among older adults which collects data from multiple regions, the SWELL Study may contribute to knowledge building and service planning at both a local and national level. The data will provide a comprehensive and comparative picture of current sexual health among older adults in China. We anticipate the SWELL Study to generate high-quality evidence to inform sexual health strategies for Chinese older adults.

As an innovative study about sexual health among Chinese older adults, the SWELL Study may be susceptible to challenges arising from conservative stereotypes about sexual health. We hope to ease these challenges by standardizing and testing operating procedures in advance, periodic study monitoring, evaluation processes, and interdisciplinary cooperation in public health, implementation science, and social sciences, ensuring stakeholder involvement and support at all stages of the study. The protocol of the SWELL Study incorporates a multi-tiered recruitment strategy and comprehensive risk mitigation procedures. It could extend current literature to find a solution for complex problems about sexual health among Chinese older adults. Furthermore, standardized protocol, data collection, and operating procedures will ensure high-quality data. Consistent with a holistic geriatrics approach, sexual health issues cannot be addressed alone. The experts from multidisciplinary domains in
SWELL Study, including Public Health, Clinical Medicine, Social Medicine, Health Service Management, Epidemiology, Behavioral Science, and Health Statistics, will provide optimal study oversight.

We believe the findings of the SWELL Study will guide practice decisions on sexual health promotion among older adults in China. The results will also contribute to comprehensive and evidence-based recommendations on policies, practices, and strategies to promote sexual health among older adults. This research protocol may serve as a valuable guide for other researchers interested in replicating the outlined cross-sectional methodology in order to understand the sexual health status better among older adults.

Ethics and dissemination

Ethical considerations

This study (including verbal informed consent) was approved by the Human Research Ethics Committee of the School of Public Health (Shenzhen), Sun Yat-sen University (approval number SYSU-PHS[2019]006) (Appendix 1). All procedures contributing to this work comply with the ethical standards of relevant national and institutional committees on human experimentation and with the Helsinki Declaration. The anonymity and confidentiality of the participants in this study will be ensured and maintained according to laws and regulations. Verbal informed consent will be obtained from all participants before any study procedure.

Dissemination
Findings from the SWELL Study will be disseminated widely through peer-reviewed scientific journals and at national and international conferences.

**Abbreviations**

SWELL: Sexual well-being among older adults in China

OALHIV: Older adults living with HIV

STIs: sexually transmitted infections

HIV: Human immunodeficiency virus

CDC: Center for Disease Control and Prevention

ID: Identification

Natsal: British National Surveys of Sexual Attitudes and Lifestyles

**Figure legends**

Figure 1. The multi-stage sampling framework of SWELL study

Figure 2. The study procedures of SWELL study

**Supplementary information**

Appendix 1. Human Research Ethics Committee of the School of Public Health (Shenzhen), Sun Yat-sen University approval document

Appendix 2. The function of barcodes during the investigation procedures

**Declarations**

Consent to publish: Not applicable.

Availability of data and materials
The data collected in this study will not be publicly available. However, the corresponding author can be contacted for de-identified data upon reasonable request.

**Competing interests statement**

The authors declare that they have no competing interests.

**Funding**

This study was supported by the Natural Science Foundation of China International/Regional Research Collaboration Project [72061137001], Natural Science Foundation of China Excellent Young Scientists Fund [82022064], Non-profit Central Research Institute Fund of Chinese Academy of Medical Sciences [2020-JKCS-030], Natural Science Foundation of China Young Scientist Fund [81703278], the National Science and Technology Major Project of China [2018ZX10721102], the Sanming Project of Medicine in Shenzhen [SZSM201811071], the High Level Project of Medicine in Longhua, Shenzhen [HLPM201907020105], the National Key Research and Development Program of China [2020YFC0840900], the Shenzhen Science and Technology Innovation Commission Basic Research Program [JCYJ20190807155409373], Special Support Plan for High-Level Talents of Guangdong Province [2019TQ05Y230], and the Fundamental Research Funds for the Central Universities [58000-31620005]. All funding parties did not have any role in the study design or data explanation.

**Authors’ contributions**
HZ conceived the study. BW, XP, BL, LF, TT, JL, and TS drafted the protocol. YL, XL, SW, WZ, XX, GC, GW, LO, MY, YC, YW, XM, JT, DW, WT, XM, and HZ revised the manuscript. All authors have read and approved the final manuscript.

Acknowledgments

We thank our partners, including Chongqing CDC, Tianjin CDC, Baiyun District CDC, Guangzhou, Guangdong Association of STD & AIDS Prevention and Control, Shizhong District CDC, Jinan, Shanghai Jiao Tong University, and Guangdong Youth Sexual Health Union. We thank Yu Jie from School of Sociology and Anthropology, Xiamen University for his comments in the preparation of this protocol. We thank all participants who made this research possible.

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BW, XP, BL, LF, and TT contributed equally to this work.

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Correspondence to Dan Wu, Xiaojun Meng, Maohe Yu, Guohui Wu, Yong Cai, Huachun Zou.

REFERENCE


4 Galinsky AM, Waite LJ. Sexual activity and psychological health as mediators of the relationship between physical health and marital quality. Journals of


doi:10.1080/02701960.2017.1340885


doi:10.1016/j.maturitas.2015.05.004


doi:10.3389/fmed.2022.851635


### Sampling Frame for Subdistrict Units

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### City Code

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Investigators recruitment

Training & Examination

Qualification certificate

Participants recruitment

Informed consent

Survey phase

Specimen sampling phase

Specimen testing phase

Survey data

- Age ≥50 years
- Have ever had any sexual activities
- Understand the questionnaire
- Agree to provide a blood sample
公共卫生学院（深圳）医学伦理委员会审批件

编号：中大公卫（深圳）医伦（2019）第006号

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<tr>
<td>研究内容及意义</td>
<td>医学技术的发展及寿命的延长，使得老年人群可能在很长一段时间内仍然保持持续活跃的性生活，而身体机能的衰老带来的影响性健康状况的问题日渐凸显。本研究旨在通过参与性社区驱动方法，借助多学科跨地区合作的方式调查中英两国老龄人口性健康状况，通过比较双方差异，寻找双方遇到的难点，并通过离散选择实验（DCE）及众包竞赛的方式寻找改善两国性健康服务的途径，为改善中英两国老龄人口性健康服务提供政策建议。</td>
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医学伦理委员会审批意见：
同意该项目在获得研究对象知情同意的情况下开展
Barcode 1
For survey instrument
ID 01 76 408 23 ABLE 01

Barcode 2
For specimen sampling
ID 01 76 408 23 ABLE 02

Barcode 3
For specimen testing
ID 01 76 408 23 ABLE 03

Survey instrument
Specimen
Test report confirmation form
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| **Title and abstract** | 1 | *(a)* Indicate the study’s design with a commonly used term in the title or the abstract  
*(b)* Provide in the abstract an informative and balanced summary of what was done and what was found | 1, 4-5 |
| **Introduction** | 2 | Explain the scientific background and rationale for the investigation being reported | 7 |
| **Objectives** | 3 | State specific objectives, including any prespecified hypotheses | 8 |
| **Methods** | 4 | Present key elements of study design early in the paper | 8 |
| **Setting** | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 8 |
| **Participants** | 6 | *(a)* Give the eligibility criteria, and the sources and methods of selection of participants | 10-11 |
| **Variables** | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 11-12 |
| **Data sources/measurement** | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | 11 |
| **Bias** | 9 | Describe any efforts to address potential sources of bias | 10-11 |
| **Study size** | 10 | Explain how the study size was arrived at | 9-10 |
| **Quantitative variables** | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | N/A |
| **Statistical methods** | 12 | *(a)* Describe all statistical methods, including those used to control for confounding  
*(b)* Describe any methods used to examine subgroups and interactions  
*(c)* Explain how missing data were addressed  
*(d)* If applicable, describe analytical methods taking account of sampling strategy  
*(e)* Describe any sensitivity analyses | 17 |
| **Results** | 13* | *(a)* Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed  
*(b)* Give reasons for non-participation at each stage  
*(c)* Consider use of a flow diagram | N/A |
| **Descriptive data** | 14* | *(a)* Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders  
*(b)* Indicate number of participants with missing data for each variable of interest | N/A |
| **Outcome data** | 15* | Report numbers of outcome events or summary measures | N/A |
| **Main results** | 16 | *(a)* Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | N/A |
(b) Report category boundaries when continuous variables were categorized

(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period

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**Discussion**

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*Give information separately for exposed and unexposed groups.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.