

# BMJ Open Sexual well-being among older adults in China (SWELL): protocol for a multicenter cross-sectional 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 multicentre 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. A multistage sampling approach is used in the SWELL Study. We will collect a questionnaire about sexual health (sexual knowledge, sexual attitude, sexual behaviours, sexually transmitted infections, etc). Blood specimens will be tested for sex hormones (estradiol for women, testosterone for men), biochemical items (eg, cholesterol, triglycerides, low-density lipoprotein, high-density lipoprotein, urea, creatinine and uric acid) and syphilis (determined by toluidine red unheated serum test and Treponema pallidum particle agglutination test). 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 anonymised, 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.

## 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.<sup>1–3</sup>

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The sexual well-being among older adults in China Study is the first study to collect, analyse and synthesise 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.

As is discovered in these studies, healthy and enjoyable sexuality could improve multiple aspects of health,<sup>3,4</sup> such as protecting mental health<sup>5</sup> and cognitive function,<sup>6,7</sup> reducing the risk of cardiovascular disease<sup>8</sup> and reducing all-cause mortality.<sup>9</sup> The health benefits of sex may be more prominent among older adults compared with those who are younger.<sup>3</sup> Compared with sexually inactive peers, sexually active older adults have better functional status and moods.<sup>10</sup>

China is striding towards an ageing society. By 2050, the older adults will account for 26.1% of the country's total population.<sup>11</sup> The increasingly ageing 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.<sup>10,12</sup> At the same time, immunosenescence (ie, decreased immune function due to ageing) makes older adults more vulnerable to infections, including sexually transmitted infections (STIs).<sup>13</sup> The incidence of STIs in

older adults is rising, making it a formidable public health challenge.<sup>14 15</sup> 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 behaviours, 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 multi-stage 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 ANALYSES

### 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, OALHIV, healthcare providers, social workers and research administrators from the 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 Declaration of Helsinki. 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) (online supplemental appendix

1). Data will be anonymised, 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,<sup>16</sup> we used 20% and 32% as the rate of sexual dysfunction in men and women, which are denoted by P in the following formula:

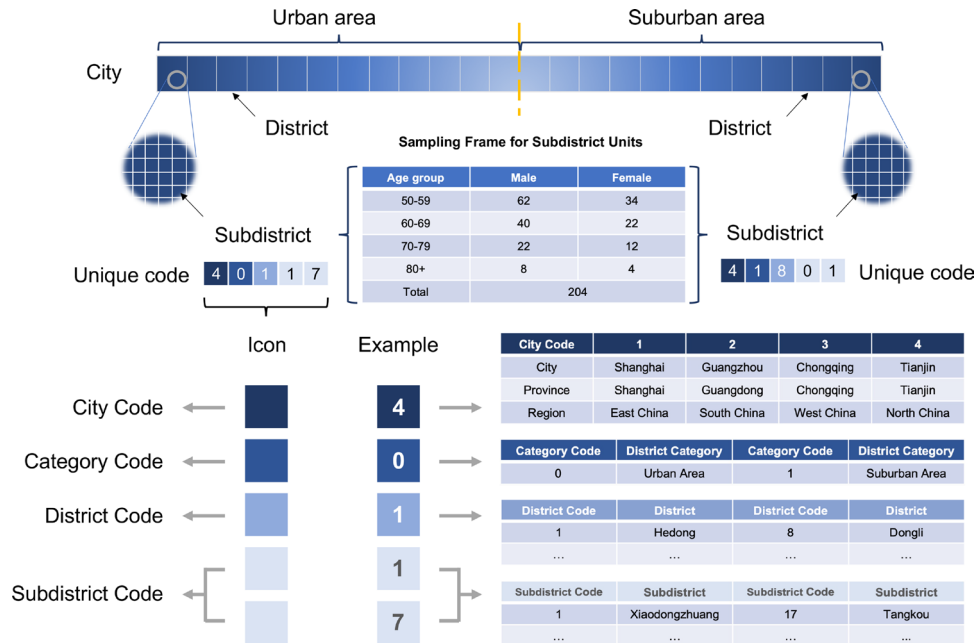
$$N = \frac{z_{\alpha}^2 \cdot P \cdot (1-P)}{d^2},$$

where,  $z_{\alpha}$  = Z-statistic, P = feature prevalence and d = accuracy level.

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 behaviours among OALHIV,<sup>17</sup> we used 33% for the prevalence of sexual activeness (ie, having sexual activity in the past 12 months) as P in the formula. Overall, 600 OALHIV (400 men and 200 women) will be recruited to the SWELL Study. A total of 3540 older adults will be recruited into the SWELL Study.

### Sampling method

Multistage 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 (ie, 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 V.9.4. A total of 16 survey sites are finally selected. The multistage sampling frame is shown in [figure 1](#). At each survey site, the stratifying variables—age and gender—are used to ensure the representativeness



**Figure 1** The multistage sampling framework of sexual well-being among older adults in China Study.

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  $\geq 50$  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 the SWELL Study is adapted from the UK Natsal-3 survey instrument.<sup>18</sup> Multi-domain variables will be collected, including sociodemographic characteristics (eg, gender, age, relationship status, monthly income, education levels and employment status), general health status, sexual lifestyles characteristics (eg, sexual experience, sexual behaviours, quality of sexual life, sexual needs and attitude toward sex) and sexual health indicators (eg, sex education levels, previous STIs, sexual health service needs). Different from Natsal-3, which is based on the whole population (aged 16–74 years), the 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 localised the survey instrument through a small sample presurvey (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 categorised 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.<sup>19</sup>

#### 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 min qualification test.

#### Informed consent

Participants are recruited by local Centers for Disease Control and Prevention (CDCs) or non-governmental organisations. 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 online supplemental 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

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

Survey instruments content	Natsal-3	SWELL
Sociodemographics	√	√
General health, health conditions, medications taken, medical procedures	√	√
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.

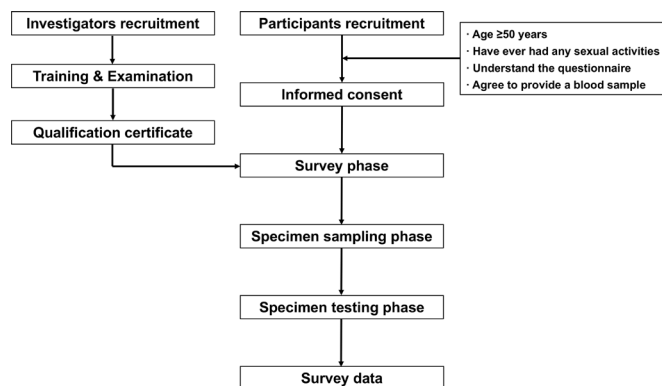
‡Questions related to the HPV vaccination were not applicable in the SWELL Study. HBV and HCV infection status were included in this part in the SWELL Study.

§The presurvey showed that the prevalence was too low and was therefore excluded from the SWELL study.

HBV, hepatitis B virus; HCV, hepatitis C virus; HPV, human papillomavirus; STIs, sexually transmitted infections; SWELL, sexual well-being among older adults in China.

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 people living with HIV (PLHIV) undergo regular physical examinations and tests for syphilis. Their clinical data together with laboratory testing

**Figure 2** The study procedures of SWELL Study.

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 ¥50 (US\$7.5). Each specimen will be labelled 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 analysed using Combas C702 automatic chemical analyser. 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, Washington, 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 (eg, time since HIV diagnosis, duration on ART, viral load, etc), diagnosis of comorbidities (eg, arthritis, heart attack, coronary heart disease, angina, other forms of heart disease, hyperuricaemia, hypertension, stroke, diabetes, any other muscle or bone disease lasting longer than 3 months and chronic airways disease), STIs (eg, syphilis, chlamydia and gonorrhoea) and opportunistic infections (eg, herpes zoster, bacterial pneumonia, pulmonary and extrapulmonary 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 prespecified 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 1 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 on 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 on survey completion that provides tips for healthy ageing and recommendations about a healthy lifestyle.

## Data security and data management

### Data download

The data will be exported from the digital platform in .CSV format on 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 behaviours, 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 (V.24.0 for macOS) and SAS (V.9.4 for macOS). The qualitative analysis will be conducted by the qualitative analysis software, including Atlas.ti (V.8.0) and NVivo (V.12.0). Simple descriptive statistics will be used to describe the distributions of variables. Meanwhile, the associations between independent variables (eg, socio-demographic characteristics and general health status) and the outcome variables (eg, sexual lifestyles characteristics and sexual health indicators) will be analysed by multivariable logistics models. Subgroup analysis will be performed by studying the differences between age, sex (female/male), HIV status (ie, 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 behaviours have come a long way since the pioneering but methodologically problematic studies carried out by Kinsey in the USA in 1948.<sup>20</sup> The emergence of the HIV/AIDS epidemic in the 1980s provided the imperative for collecting reliable data on sexual behaviours, as epidemiologists and public health specialists recognised that the implementation science for solving sexual health problems needs data support and theoretical basis.<sup>20</sup>

In an ageing 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 analysing data from a multi-centre 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 standardising 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, standardised 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 the 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) (online supplemental 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 Declaration of Helsinki.

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.

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**Contributors** 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 and HZ revised the manuscript. All authors have read and approved the final manuscript.

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**Competing interests** None declared.

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

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