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UNITED KINGDOM · CHINA · MALAYSIA

An exploration of the role of the primary care physician in Type 2 diabetes care in Ningbo, China. A qualitative study of patient and practitioner perspectives

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Short title: T2DM Primary Care Ningbo

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STUDY PERSONNEL AND CONTACT DETAILS

Sponsor:
Contact name
University of Nottingham
Ms Angela Shone
Head of Research Governance
Research and Graduate Services
King's Meadow Campus
Lenton Lane
Nottingham
NG7 2NR

Chief investigator:
Professor Richard Hubbard
Professor of Respiratory Epidemiology, Faculty of Medicine & Health Sciences
Phone: 0115 823 1710
Email: Email: richard.hubbard@nottingham.ac.uk

Co-investigators:
Dr A K Woolley
Academic Clinical Fellow in Primary Care
akwoolley@gmail.com
07825558693

Dr Prit Chahal
Associate Post Graduate Dean, Health Education East Midlands
Pritpal.Chahal@hee.nhs.uk

Dr Gloria Tu
Post CCT GP Fellow
gloriat@doctors.org.uk

Punam Chahal
Research support and Allied Healthcare Professional
punam.chahal1@virginmedia.com

Priya Chahal
Research assistant
priya.chahal95@gmail.com

Dr Kaushik Chattopadhyay
Assistant Professor in Evidence Based Healthcare, Faculty of Medicine & Health Sciences
Kaushik.Chattopadhyay@nottingham.ac.uk

Dr Kai Huang
GP, Ningbo No. 1 Hospital
huangkaihra@163.com

Dr Jinguo Chu
Senior Educator, Ningbo No. 1 Hospital
chujg@126.com

Dr Jialin Li
lijialin@sina.com
Department of Endocrinology and Metabolism,
Ningbo First Hospital, Ningbo, PR China

Dr Jianping Chu - chujianping@medmail.com.cn
Diabetology Department, Ningbo No.1 Hospital

Dr Li Li - lilyningbo@163.com
Diabetology Department, Ningbo No.1 Hospital

Study Coordinating Centre: Division of Epidemiology & Public Health, School of Medicine

SYNOPSIS

Title	The primary care physician in Type 2 diabetes care in Ningbo, China. A qualitative study of patient and practitioner perspectives
Short title	T2DM Primary Care Ningbo
Chief Investigator	Professor Richard Hubbard
Objectives	1) To explore patient perspectives on the current role of GPs in care of Type 2 diabetes patients accessing medical care in Ningbo 2) To explore perspectives of GPs in Ningbo about the role of primary care in management of patients with type 2 diabetes 3) To understand how the role of primary care in Type 2 Diabetes may be developed, from both a patient and GP perspective
Study Configuration	Single Centre
Setting	Primary care
Sample size estimate	30-50 qualitative interviews will be undertaken, equally split between patients and GPs. No formal sample size calculation is needed. This is a pragmatic target based on study time and budgetary constraints and is anticipated (from experience in previous, similar studies) to achieve data saturation.
Number of participants	Maximum of 50 , depending on when data saturation is achieved
Eligibility criteria	For Patients Diagnosed with type 2 diabetes Aged over 18 No cognitive impairment Able to communicate verbally with the researcher via a local translator (if required) For Physicians: Primary Care Physician Experience of treating patients with T2DM Aged over 18 No cognitive impairment Able to communicate verbally with the researcher via a local translator (if required)

Description of interventions	Participants will undertake a single, face-to-face, semi–structured interview with one or two researchers and a local language translator, if required by the participant. The interview will last approximately 30 minutes.
Duration of study	Overall data collection period will be for 3 weeks commencing 4th December 2017. Per participant duration will be 30 minutes (planned interview duration)
Methods of analysis	Interviews will be transcribed and analysed using qualitative, thematic coding and inductive analysis.

ABBREVIATIONS

CI Chief Investigator overall

CRF Case Report Form

GCP Good Clinical Practice

NHS National Health Service

PI Principal Investigator at a local centre

PIS Participant Information Sheet

REC Research Ethics Committee

R&D Research and Development department

UoN University of Nottingham

T2DM Type Two Diabetes

HCP Health Care Professional

GP General Practitioner

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STUDY BACKGROUND INFORMATION AND RATIONALE

Type 2 diabetes (T2DM) is a chronic condition with multisystem complications, which presents a global public health issue. The global prevalence of diabetes* among adults over 18 years of age has risen from 4.7% in 1980 to 8.5% in 2014 (Mathers & Loncar, 2006). Symptoms of T2DM include excessive excretion of urine (polyuria), thirst (polydipsia), constant hunger, weight loss, vision changes, and fatigue. Over time diabetes may affect the heart, blood vessels, kidneys, eyes and nerves causing complications such as heart attack, stroke, amputations, end stage kidney failure and blindness. Lifestyle measures and adherence to readily available medications may delay the onset of diabetes or the development of these complications.

In China, the prevalence of diabetes has increased significantly in the last 30 years (Weng et al 2016), and is now estimated at 9.7% - above the global average. T2DM accounts for over 90% of the total diabetic population. In 2016 the Chinese Diabetes Society produced a set of standards for care of T2DM in China (Weng et al 2016).

In the UK T2DM is often managed solely in primary care. (NICE 2014) This has benefits to the patient in terms of access to timely, nearby access to medical support regarding their condition. At a National Health Service level, the burden on secondary care facilities is reduced so they are able to concentrate resources on the management of complex, difficult to treat cases.

In China however, the role of the general practitioner in the health care system is very different. Recent research has found an overall lack of public respect for general practitioners in China, with most patients still choosing to go directly to the hospital, where they perceive they will receive better treatment (Sandars et al 2016). Standards of care for T2DM care are broadly comparable between the UK and China (NICE 2014, Weng et al 2016) suggesting the potential of a larger role to play for primary care in the management of patients with T2DM in China.

The current project intends to further our understanding the current model of primary care for T2DM in China, using Ningbo as an example. We will explore the priorities for development of patients and GPs and this will inform future interventions in the area, including the possibility of specialist training for primary care physicians in the area of T2DM care.

This understanding will be fundamental to developing the delivery of primary care for T2DM which is anticipated to enable more patients to be seen in shorter time frames, and by general practitioners in local treatment centres (without having to make inconvenient and costly journeys to specialist centres).

STUDY OBJECTIVES AND PURPOSE

PURPOSE

To use qualitative research methods to explore patient and GP's perspectives on the current role of primary care in the management of patients with T2DM in Ningbo, China and identify priorities for future development.

PRIMARY OBJECTIVE

1) To explore patient perspectives on the current role of primary care physicians in care of Type 2 diabetes patients accessing medical care at Ningbo No. 1 Hospital

2) To explore perspectives of GPs in Ningbo about the role of primary care in management of patients with type 2 diabetes

3) To understand how the role of primary care in Type 2 Diabetes may be developed, from both a patient and GP perspective

SECONDARY OBJECTIVES

none

STUDY DESIGN

STUDY CONFIGURATION

The study will be a Single centre Study at Ningbo No. 1 hospital, Ningbo, China. Participants will be recruited in two Groups – patients and GPs. Semi-structured interviews will be used to explore the range of perspectives held and develop answers to the study questions.

STUDY MANAGEMENT

The Chief Investigator, Professor Richard Hubbard, is based in the Faculty of Medicine & Health Sciences at Nottingham University and has overall responsibility for the study and shall oversee all study management. The data custodian will be the Chief Investigator.

Local project team in China consist of a group of medical doctors, from both China and the UK, experienced in management of patients with T2DM. have previous research experience and have undertaken additional training specific to the study methodology. The local research team also includes an allied healthcare professional and a research assistant.

There will not be a separate Study management group, since it is not a clinical trial.

DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

Study Duration: The total data collection period will be for 3 weeks from 4th December 2017. Following completion of data collection, data analysis is expected to continue for a further 2 months prior to the anticipated production of the project report in February 2018.

Participant Duration: Participant duration will begin at consent and continue for the duration of the interview, which is anticipated to be 30mins per participant.

End of the Study

The end of the study will occur when the final participant has been recruited and interviewed, or when data saturation has been achieved.

SELECTION AND WITHDRAWAL OF PARTICIPANTS

Recruitment

Approach of patient participants: Participants will be recruited from primary care facilities in Ningbo. Initial approach will be by a member of the usual care team. This setting is an ideal

setting for the study as it allows the research team access to a large concentration of potential participant in order to complete the required number of interview within the project time frame. The usual medical team is available to the patient if they require them and the facilities are available to undertake interviews in a private room.

Patients expressing an interest in the study will have eligibility confirmed and will be given a more detailed patient information leaflet and consent form to review (in the local language). They will have the opportunity to ask questions of the researcher via a local language interpreter. Prospective participants will be offered the chance to participate after their medical appointment (to ensure no delay to care). The medical notes of the patient will not be reviewed by the research team. Following consent, the interview be undertaken immediately, in a private room.

Approach of GP participants: These will be approached via local contacts. GPs who express an interest in the study will have their eligibility confirmed and will be given a more detailed patient information leaflet and consent form to review (in the local language). They will have the opportunity to ask questions of the researcher via a local language interpreter. Participation will occur on a single day agreed mutually between researcher and prospective participant.

All:
It will be explained to the potential participant that entry into the study is entirely voluntary and that their treatment and care (or employment if GP) will not be affected by their decision. It will also be explained that they can withdraw at any time but attempts will be made to avoid this occurrence. In the event of their withdrawal it will be explained that their data collected so far cannot be erased and we will seek consent to use the data in the final analyses where appropriate.

Eligibility criteria

Inclusion criteria

For Patients:
Diagnosed with Type 2 Diabetes
Able to communicate verbally with researcher via a local translator (if required) including to give informed consent

For GPs:
Experience of treating patients with T2DM
Able to communicate verbally with researcher via a local translator (if required) including to give informed consent

Exclusion criteria

For all:
Cognitive impairment or other condition suggesting vulnerability or inability to give informed consent
Acute illness
Aged under 18 (no upper age limit)

Expected duration of participant participation

Study participants will be participating in the study for 30 minutes.

Participant Withdrawal

Participants may be withdrawn from the study either at their own request or at the discretion of the Investigator. The participants will be made aware that this will not affect their future care. Participants will be made aware (via the information sheet and consent form) that should they withdraw the data collected to date cannot be erased and may still be used in the final analysis.

Informed consent

All participants will provide written informed consent for themselves, since no underage, cognitively impaired or otherwise vulnerable participants will be included. Patient information and consent forms will be provided in the local Ningbo Language (Mandarin). The Investigator will explain the details of the study and provide a participant information sheet in the local language, ensuring that the participant has sufficient time to consider participating or not. The Investigator will answer any questions that the participant has concerning study participation. The consent form will be signed and dated by the participant before they enter the study.

Written informed consent will be collected from each participant before they are interviewed. One copy of this will be kept by the participant, one will be kept by the Investigator, and a third will be retained in the patient's hospital records.

Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the study, continuing consent will be obtained using an amended Consent Form which will be signed by the participant.

STUDY REGIMEN

Schematic diagram of study steps is provided below. All steps occur outside of usual care. Usual care will continue to occur, undisrupted by the study, with no limitation of concomitant treatments, for all patient participants (not applicable for GP participants)

IDENTIFICATION AND RECRUITMENT

Identification of potential participant

↓

Potential participant expresses interest in study

↓

Confirmation of Eligibility
Written information provided

↓

Participant given time to read information and may ask questions to researcher via translator if desired

↓

Consent form completed

↓

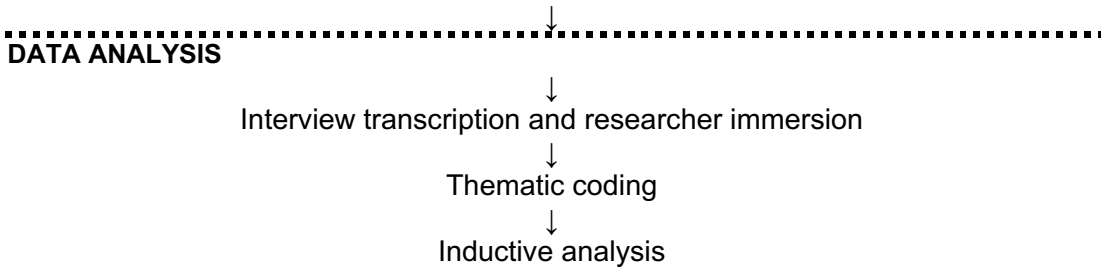
DATA COLLECTION

↓

Face - to - face semistructured interview (30 mins)

↓

Study participation ends. No further follow up.



Interviews will be conducted in a private room at Ningbo no. 1 Hospital and recorded (with consent) using a Dictaphone. Participants will be identified on the tape using a code. Interviews will be conducted by the researcher with the aid of a translator for local language. Recorded interviews will be transcribed by the researcher for analysis. Recordings will be deleted following transcription. Transcripts will be kept securely on a password protected computer. These are source data and will be retained in the study archives, but personal identifiers will be removed.

Compliance

Not applicable

Criteria for terminating the study

No patient safety issues that could precipitate study termination are anticipated. The study may be stopped due to issues with study conduct such as poor recruitment or loss of resources. The study does not us any materials that would require return or destruction

ANALYSES

Methods

Dr Angharad Kate Woolley, with assistance from the rest of the research team will evaluate the findings using immersion, thematic coding and inductive analysis. To ensure consistency, a subset of transcripts will be independently analysed by two researchers and findings compared. Data will be compiled in Microsoft Excel. No specific statistical analysis software will be used as it is not applicable to this study type.

No interim analyses are planned however the study may be terminated in advance of the 30th participant if the team undertaking, transcribing and coding the interviews identify that data saturation has occurred (since this is specified as an alternative end point, after which the recruitment of further participants and collection of further data would not be justified).

Sample size and justification

The target sample size of 30-50 participants (approximately equal division between patients and GP) has been suggested on the basis of researcher experience and the finding of past, similar studies that data saturation may be achieved within this number of interviews (Lee et al 2017). The suggested sample size is also pragmatic, taking account of the 3 week period available for data collection when the study team visit China, and the capabilities of the researchers involved.

ADVERSE EVENTS

The occurrence of an adverse event as a result of participation within this study is not expected and no adverse event data will be collected.

ETHICAL AND REGULATORY ASPECTS

UK Researchers will work collaboratively with local healthcare professionals in Ningbo in Development of the study procedures and interview guide to ensure that they are culturally sensitive and relevant to Chinese patients and GPs. The research team includes five medical doctors already working at Ningbo No.1 hospital who are experienced in research and have been trained in the study methodology.

It will be made clear to the participants from the outset what participation will entail and that no remuneration will be given. Participation in the study will not include any form of medical care so this cannot act as an inducement to participate.

Participant information sheets and consent forms will be translated into Chinese (Mandarin) to facilitate patient understanding of the project. Researchers will work with translators at all times to ensure ease of communication and the translator will also sign a form to confirm confidentiality.

Participant descriptions of their health conditions and healthcare experiences (as patients and professionals) may be sensitive therefore will be handled confidentially as described elsewhere in the protocol. No more sensitive information than this will be collected.

Since it is not relevant to the study, the researcher will not access the patients' medical records, thus removing the possibility of disruption of this confidential data.

The project is being undertaken at part of a larger global health exchange programme between the University of Nottingham and Ningbo No.1 hospital. A comprehensive risk assessment of the wider project has been undertaken to ensure researcher safety at all times. Travelling researchers will be responsible for arranging their own personal travel insurance. No lone working will occur.

ETHICS COMMITTEE AND REGULATORY APPROVALS

The study will not be initiated before the protocol, consent forms and participant information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), and the local research and development department in No. 1 Hospital, Ningbo. Ningbo no. 1 Hospital has a local procedure for ethical review in place and the team have worked closely with University of Nottingham Researchers with previous experience of the Ningbo No. 1 hospital research ethics committee and also with local Ningbo research physicians to ensure that local procedures are adhered to. All study documents will be translated into Chinese for review by the Ningbo No. 1 Hospital ethics committee prior to the research being commenced. NHS Ethics is not applicable as the study will not use NHS patients.

Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets (if appropriate) have been reviewed and received approval / favourable opinion from the REC and R&D departments. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately

providing that the REC are notified as soon as possible and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the Department of Health Research Governance Framework for Health and Social care, 2005.

INFORMED CONSENT AND PARTICIPANT INFORMATION

The process for obtaining participant informed consent will be in accordance with the REC guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced. The investigator and the participant shall both sign and date the Consent Form before the person can participate in the study.

The participant will receive a copy of the signed and dated forms and the original will be retained in the Study records. The medical notes of the patient will not be handled by the researcher.

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasize to them that consent regarding study participation may be withdrawn at any time without penalty or affecting the quality or quantity of their future medical care, or loss of benefits to which the participant is otherwise entitled. No study-specific interventions will be done before informed consent has been obtained.

The investigator will inform the participant of any relevant information that becomes available during the course of the study, and will discuss with them, whether they wish to continue with the study. If applicable they will be asked to sign revised consent forms.

If the Consent Form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Consent Form by the REC and use of the amended form (including for ongoing participants).

RECORDS

Case Report Forms

Each participant will be assigned a study identity code number, for use on study documents and the electronic database. The documents and database will also use their initials (of first and last names separated by a hyphen or a middle name initial when available and birth year. The full DOB will not be required due to the risk of participant identification. Since this is a small, single centre study it is unlikely that initials and birth year will be shared between participants.

There is not a “Case Report Form” since this is not a clinical trial. Per participant study documents will include:

- Consent form – this will necessarily the full name of the participant and date of enrolment.
- Transcript of recording – this will be identified only by code number

These documents will be initially produced as hard copies and kept in secure, locked files. Coded documents (eg. Transcripts) and decoding list will be kept separately.

The researcher will ensure that the identifiers used all match with the allocated study number.

As soon as is practicable the hard copies with be stored electronically and stored on University of Nottingham computers and backed on University of Nottingham servers.

Participant documents will be treated as confidential documents and held securely in accordance with regulations. The investigator will make a separate confidential record of the participant's name, date of birth, local hospital number, and Participant Study Number, to permit identification of all participants enrolled in the study (including contact details), in case additional follow-up is required.

Participant documents shall be restricted to those personnel approved by the Chief or local Investigator and recorded as such in the study records.

Participant documents are used to record study data and are an integral part of the study and subsequent reports and therefore, must be legible and complete.

All paper forms shall be filled in using black ballpoint pen. Errors shall be lined out but not obliterated by using correction fluid and the correction inserted, initialled and dated.
The Chief or local Investigator shall sign a declaration ensuring accuracy of data recorded in the participant documents.

Source documents

Source documents shall be filed at the investigator's site and may include but are not limited to, consent forms, study records, field notes, interview transcriptions and audio records. Only study staff shall have access to study documentation other than the regulatory requirements listed below.

Direct access to source data / documents

All participant and source documents shall made be available at all times for review by the Chief Investigator, Sponsor's designee and inspection by relevant regulatory authorities.

DATA PROTECTION

All study staff and investigators will endeavour to protect the rights of the study's participants to privacy and informed consent, and will adhere to the Data Protection Act, 1998. The CRF will only collect the minimum required information for the purposes of the study. CRFs will be held securely, in a locked room, or locked cupboard or cabinet. During transit (eg. On return from China to UK), study documents will be kept in a locked file and backed up electronically. Access to the information will be limited to the study staff and investigators and any relevant regulatory authorities (see above). Computer held data including the study database will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one way encryption method).

Information about the study in the participant's medical records / hospital notes will be treated confidentially in the same way as all other confidential medical information.

Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

QUALITY ASSURANCE & AUDIT

INSURANCE AND INDEMNITY

The University of Nottingham as research Sponsor indemnifies its staff, research participants and research protocols with both public liability insurance and clinical trials insurance. These policies include provision for indemnity in the event of a successful litigious claim for proven non-negligent harm.

NHS indemnity does not apply since the study is not being conducted within the NHS.

STUDY CONDUCT

Study conduct may be subject to systems audit for inclusion of essential documents; permissions to conduct the study; CVs of study staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria, timeliness of visits); accountability of study materials and equipment calibration logs.
The Study Coordinator/Academic Supervisor, or where required, a nominated designee of the Sponsor, shall carry out a site systems audit at least yearly and an audit report shall be made.

STUDY DATA

Monitoring of study data shall include confirmation of informed consent; source data verification; data storage and data transfer procedures; local quality control checks and procedures, back-up and disaster recovery of any local databases and validation of data manipulation. The Study Coordinator/Academic Supervisor,, or where required, a nominated designee of the Sponsor, shall carry out monitoring of study data as an ongoing activity.

Entries on participant documents will be verified by inspection against the source data. A sample of participant documents (10%) will be checked on a regular basis for verification of all entries made. In addition the subsequent capture of the data on the study database will be checked. Where corrections are required these will carry a full audit trail and justification.

Study data and evidence of monitoring and systems audits will be made available for inspection by the REC as required.

RECORD RETENTION AND ARCHIVING

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Code of Research Conduct and Research Ethics, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

The study documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include all anonymised audio recordings, study databases and associated meta-data encryption codes.

DISCONTINUATION OF THE STUDY BY THE SPONSOR

The Sponsor reserves the right to discontinue this study at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice as appropriate in making this decision.

STATEMENT OF CONFIDENTIALITY

Individual participant medical or personal information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.

Participant confidentiality will be further ensured by utilising identification code numbers to correspond to treatment data in the computer files.

Such medical information may be given to the participant's medical team and all appropriate medical personnel responsible for the participant's welfare.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Data generated as a result of this study will be available for inspection on request by the participating physicians, the University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

PUBLICATION AND DISSEMINATION POLICY

Following completion of the study, the findings will be compiled in a report which will be presented to the study funders. Further dissemination of the study findings will occur by presentation at relevant medical conferences eg. Royal College of General Practitioners (RCGP) Annual Conference and World Organization of Family Doctors (WONCA) Annual conference. Furthermore we aim to publish the findings of the study in a relevant global health publication. Participants will not be identified in any publications.

USER AND PUBLIC INVOLVEMENT

Due to logistical constraints (team will arrive in China only a few days prior to study start) and the small scale nature of this project, formal PPI work has not been undertaken. However the existing literature on Chinese diabetes care was reviewed and local Chinese healthcare professionals involved in formulation of the research question, protocols and interview guides to ensure their relevance and cultural sensitivity. PIL and consent form will be translated and checked for comprehensibility by a Chinese speaking "lay" person. The interview "guide" is exactly this, and will be adapted during the course of the study according to identified participant need The initial interviews will serve as a "pilot" of thee interview guide and changes the guide may be updated to reflect any issues encountered during the course of these interviews. Research participants will be given the opportunity to request study results when they are available.

STUDY FINANCES

Funding source

This study is funded by University of Nottingham (UK), Ningbo No. 1 Hospital, Ningbo (China) and Health Education England, East Midlands (UK).

Participant stipends and payments

Participants will not be paid to participate in the study. There will not be any hospital visits in excess of usual care.

SIGNATURE PAGES

Signatories to Protocol:

Chief Investigator: (name)_____

Signature:_____

Date: _____

REFERENCES

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