THE UNIVERSITY OF HULL

Male reproductive health: reasons why men may choose to participate in trials

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Overview

This portfolio thesis comprises of three parts: a systematic literature review, an empirical report and a reflective statement.

Part one is a systematic review in which literature relating to the empirical paper is reviewed. Due to a paucity of literature about reasons to participate in male reproductive health trials (RHTs), the broader area of reasons to participate in clinical trials, from a non-clinical sample, was reviewed. The review attempts to determine reasons why 'healthy' people participate in clinical trials and compares the findings with literature on reasons why patients participate. Recommendations are then made for future clinical trial recruitment strategies.

Part two is an empirical paper encompassing two studies. Study one aimed to test hypotheses about factors that influence male participation in RHTs, specifically masculinity and altruism. Comments from participants about their own idiosyncratic reasons were then used to triangulate findings. Study two aimed to complement study one by exploring experiences of men participating in a RHT. Thematic constructions of stigma, altruism and masculinity were considered within a decision-making framework.

Part three comprises of appendices, including a reflective summary drawing on all aspects of the research process.

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PART ONE:

Reasons for participation in clinical trials:

A systematic review of published literature from non-clinical populations

This paper was written in accordance with guidance for authors for the journal 'Trials' (Appendix 1).

Reasons for participation in clinical trials:

A systematic review of published literature from non-clinical populations

Abstract

Background: Clinical trial participation is often under-resourced and little is known about reasons why non-clinical populations take part in clinical trials. The aim was to systematically review published literatures on reasons to participate in clinical trials for a non-clinical population.

Methods: Key electronic databases (CINAHL, PsychINFO, PsychARTICLES, Medline, Scopus, and Web of Science) were searched using specific terms and articles were included based on inclusion and exclusion criteria. The quality of included articles was assessed using standardised criteria and data was extracted systematically using a data extraction form.

Results: 12 articles were included in the review (10 quantitative, 2 qualitative) and quality assessment scores ranged from 50% to 83%. The review identified the following reasons for trial (non) participation; age, gender, educational level, SES, personality, health status, time constraints, perceived burden, organisational credentials, understanding of research process, altruism, benefits, finances, personal interest and risks.

Conclusions: Comparisons were made between clinical and non-clinical populations' reasons for clinical trial participation. It seems both groups weigh up advantages and disadvantages of entering a trial when making a decision to participate, although the influence of these reasons would appear to be quite idiosyncratic. Recommendations for future research are made.

Introduction

Clinical trials are essential for today's requirement for evidence-based practice. The National Health Service (NHS) [1] defines the importance of clinical trials: 'Doctors, other health professionals and patients need evidence from clinical trials to know which treatments work best. Without this evidence, there is a risk that people could be given treatments that have no advantage, that waste NHS resources and that might even be harmful'. For the purpose of this review, clinical trials are conceptualised as 'a research study in human volunteers to answer specific health questions' [2]. This definition of clinical trials includes studies in a variety of locations (e.g. hospitals, universities, public places, people's homes) and utilising a range of methods (e.g. medical treatment, mailed survey, telephone interview).

Despite the importance of clinical trials, participation is often under-resourced [3]. An understanding of the facilitators and barriers to participation is required to enhance strategies for recruitment to clinical trials. A recently conducted a systematic literature review into clinical trials and concluded that the following strategies could improve recruitment; telephone reminders; use of opt-out, rather than opt-in; procedures for contacting potential trial participants and open designs [4]. However, the review did not account for potential differences between clinical and non-clinical populations.

Published literature on factors found to influence participation in clinical trials from the viewpoint of patients[1] and clinicians has also been reviewed [3]. A range of barriers to clinical trials for both patients and clinicians were identified (Table 1). However, the review did not identify drivers for patient participation.

[1] Patients and clinicians were recruited from the following settings; cancer, cardiovascular, smoking cessation, HIV/AIDS, obstetrics, surgery, child health, mental health, osteoporosis, multiple sclerosis, stroke, insomnia, diabetes and burns.

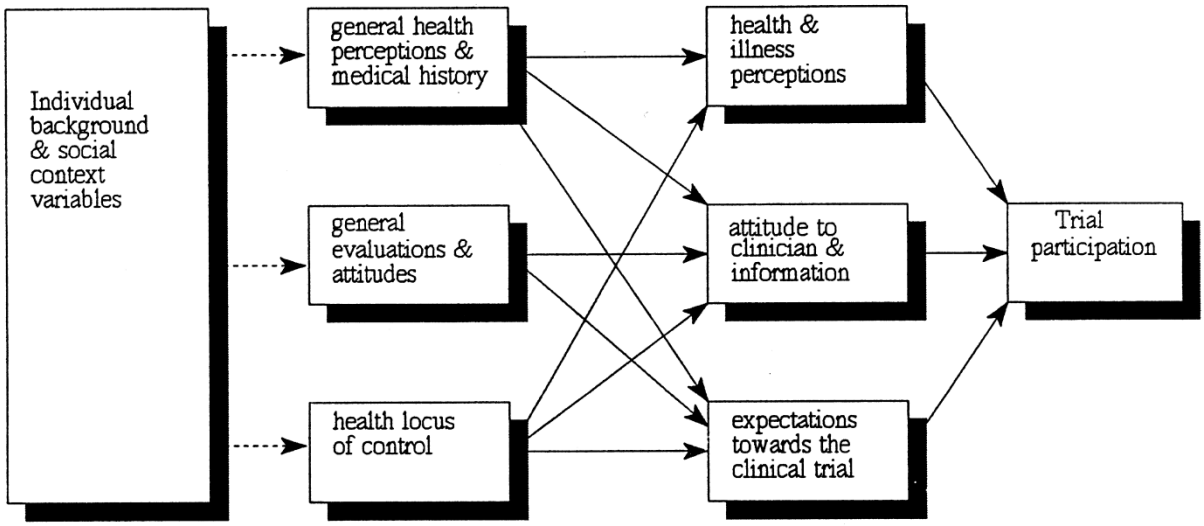
Table 1. Barriers to clinical trial recruitment for patients and clinicians.

Barrier	Number of identified papers (studies)
Patient concerns	
Additional demands on the patient:	
1. Additional procedures and appointments	13 (13)
2. Travel problems and costs	8 (8)
Patient preferences for a particular treatment (or no treatment)	15 (15)
Worry about uncertainty of treatment or trials	9 (9)
Patient concerns about information and consent	27 (26)
Clinician as barrier to patient participation	
Protocol causing problem with recruitment	14 (13)
Clinician concerns about information provision to patients	7 (7)
Clinician influencing patient decision not to join	6 (6)
Barriers to clinician participation	
Time constraints	9 (8)
Lack of staff and training	11 (11)
Worry about the impact on doctor-patient relationship	12 (11)
Concern for patients	9 (9)
Loss of professional autonomy	7 (5)
Difficulty with the consent procedure	9 (8)
Lack of rewards and recognition	5 (4)
Insufficiently interesting question	2 (2)

Reasons why patients chose to (or not to) participate in 26 clinical trials were studied [5]. The results suggested that a potential participant has a 'personal balance account' to assess before consenting to take part [5] (Figure 1). This can be calculated by the physical and emotional value a participant hopes to gain from taking part in the study, compared to non-participation, minus the risks and time burden they expect from the trial. The model suggests that background factors, beliefs, locus of control, attitudes,

expectations and perceptions have an inter-related influence on the decision to participate in a trial. When all these factors are considered, patient's decisions become 'quite predictable' [5].

Figure 1. The adapted Health Belief Model.



Factors that influence participation for a non-clinical population were not reviewed [3] [5]. Non-clinical populations are also important for clinical trials and in some cases are specifically required (e.g., research into 'healthy' people, control groups and preventative studies). A search of key electronic databases (Web of Science, 1970 to present [6]; Medline, 1950 to present [7]) suggested that to date, there has *not* been a systematic review of the literature on the reasons to take part in clinical trials from a non-clinical sample perspective. Non-clinical participant's reasons to, or not to take part in clinical trials are likely to differ from those of patient groups, due to the absence of factors related to their medical condition; such as their symptoms, treatments and contact with medical staff. As non-clinical populations are less likely to gain from

participation (i.e. new treatments), financial incentives and altruism[2] may be more influential factors in the decision making process.

In the absence of knowing about 'healthy' participants, it is also difficult to draw firm conclusions about which factors specifically influence clinical groups. Therefore, a review of published literature on the barriers and drivers to clinical trial participation for a non-clinical population is required, to formulate recruitment strategies for both clinical and non-clinical populations.

Objectives

The reviewed aimed to identify the reasons to, and not to, take part in clinical trials for a non-clinical sample.

Questions

1. What reasons are associated with participation in clinical trials for a non-clinical sample?
2. What reasons are associated with *non*-participation in clinical trials for a non-clinical sample?

Method

Data sources

A systematic search of the literature was carried out. Guidelines from the Centre for Reviews and Dissemination were used to inform the review [8]. The following electronic databases were searched; CINAHL, MEDLINE, PsychARTICLES, SCOPUS and ISI Web of Science. Ranges of databases were searched to ensure that a holistic

[2] A voluntary effort to benefit a recipient, with no expectation of reward.

approach to the research question was taken, including medical, social science and psychological perspectives. Table 2 outlines the search terms inputted into searched electronic databases.

Selection criteria

Studies were eligible for inclusion if they provided information about reasons for, or against, taking part in clinical trials. Clinical trials included all studies with human volunteers that aimed to answer specific health questions. Clinical populations were not eligible due to the potential for reasons for participation and non-participation being primarily linked to specific clinical issues and treatments. Studies including both genders were eligible to ensure a representation of potential gender influences. Studies involving children and people with carers were excluded due to the potential impact of development and differences in consenting to study participation. Qualitative and quantitative methodologies were included to ensure a broad and detailed review of the literature. Only peer reviewed full-text studies were included to increase scientific rigour. Funding and resource limitations prevented translation or the purchase of articles. Studies published before 2000 were excluded to ensure that data was recent, and studies published from the United Kingdom were within NHS reforms of the past decade, following the 'Saving Lives: Our Healthier Nation' White Paper [9].

Search strategy

Table 2. Search terms.

KEY TERMS	(OR)
Reasons (AND)	Subject Terms: "Determinants", "Attitude*", "Decision*", "Process*", "Strateg*", "Reason*", "Factor*", "Incentive*", "Benefit*", "Difficult*", "Problem*", "Obstacle*", "Barrier*", "Willing*", "Ready", "Able", "Readiness", "Agree*", "Offered", Facilitat*", "Motivat*", "Incentive*", "Drivers"
Clinical Trial (AND)	Title: "Health", Medical", "Trial", "Experiment", "Study", "Studies", "Research", "Survey".
Participation (AND)	Title: "Participation", "Subject", "Volunteer", "Participant" Subject Headings: "Research Subject Recruitment", "Research Subjects", "Research Subject Retention", "Researcher-Subject Relations".
Patients (NOT)	Title: "Patients", "Clinical Sample"

Data extraction

Data related to the aims of the review were recorded on a data extraction form designed specifically for the purposes of the review (Appendix 2). The structured form was used for both qualitative and quantitative studies.

Quality assessment

An adapted version of a 'Quality Checklist' [10] was used to guide the quality assessment of the quantitative studies (Appendix 3). The checklist was used due to its high reliability and validity scores for both randomised and non-randomised studies, and its ability to provide a full quality profile of papers. Items 4, 14, 15, 19, 21 and 23-25, were removed from the checklist as they specifically assessed intervention studies. Studies eligible for review did not always involve interventions as the review focused upon participant's reasons for taking part in clinical trials. The 'Quality Framework' [11] was used to guide the assessment of studies with qualitative methodology (Appendix 4). The 'Quality Framework' underwent a rigorous validation process and was designed for the UK government.

Data synthesis

Reasons for participation reported by included publications were grouped into themes. Themes were then compared across all included publications.

Results

Details of included and excluded studies

Figure 2 illustrates the selection process. Initial searches yielded 1541 articles. Of those, 1523 articles were excluded based on their title or abstract showing that they did not meet inclusion criteria. Seven articles were not freely available and 36 articles were re-printed. After analysis of the reprints, 24 papers were excluded based on inclusion and exclusion criteria. Articles were excluded due to the following reasons; 1) Participants were a clinical sample, 2) Participant population was too specific or difficult to generalise to a general population, 3) The article did not investigate reasons for participation.

Design of included studies

Studies with a range of designs were included in the review. Nine studies used questionnaires' [14, 15, 17, 18, 20, 21, 22, 23, 24] and two studies used semi-structured interviews [16, 19]. Study 11 analysed transcriptions from semi structured focus group discussions [12].

Measures

Included studies used different measures to evaluate reasons for (not) participating in clinical trials. Study 9 used the Minnesota Multiphasic Personality Inventory-2 (MPMI-2, [13]). Study 2 and 5 analysed the characteristics of respondents from public health questionnaires in Sweden and Denmark [14, 22]. The remaining studies used bespoke questionnaires or interviews, specifically designed to assess factors that influenced participation in respective clinical trials.

Participants

Total numbers of participants ranged from 18 to 13,604. Participants from included studies were all healthy volunteers sampled from non-clinical populations.

Figure 2. Study selection process.

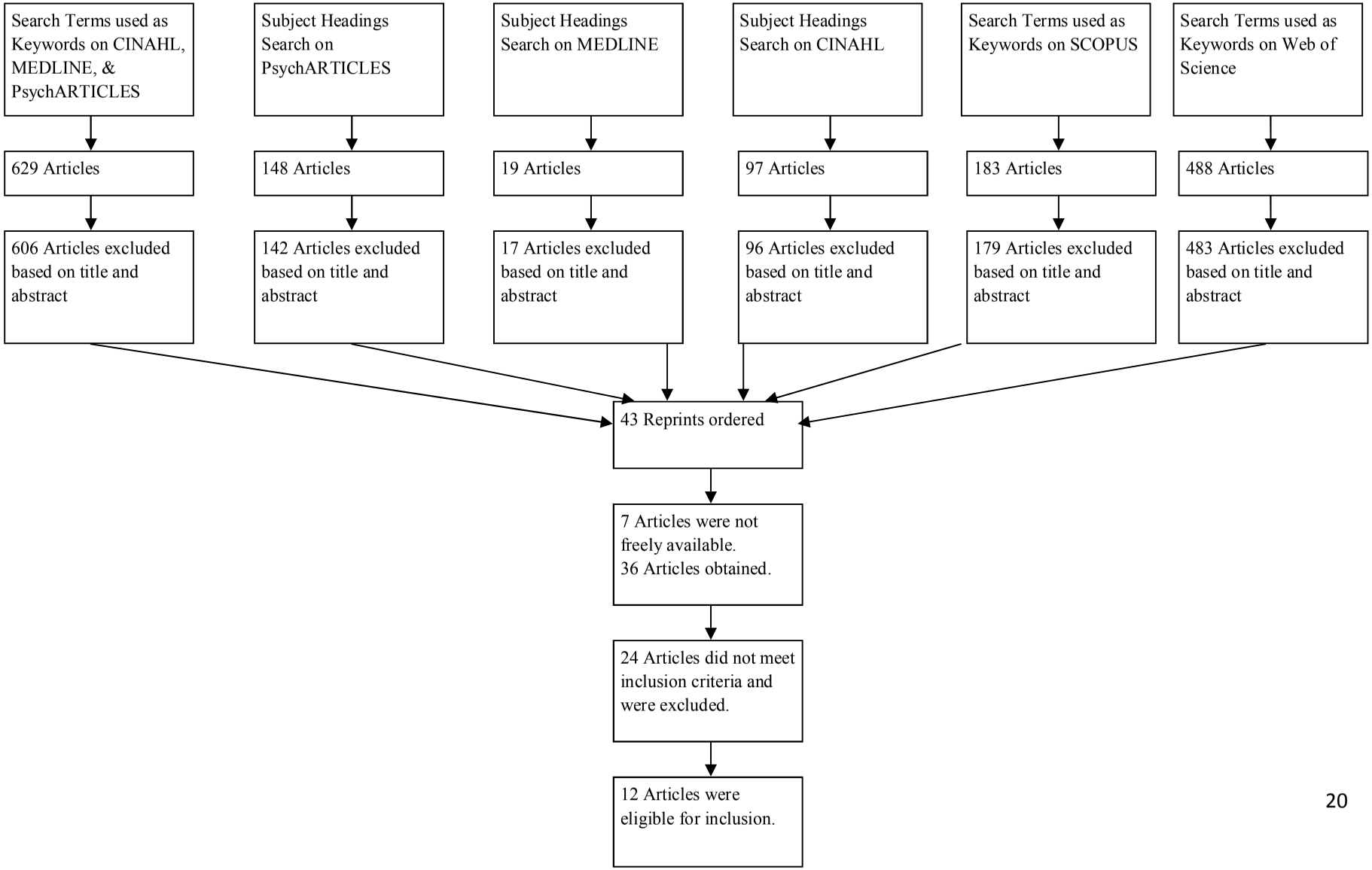


Table 3. Characteristics of reviewed studies

Study #	Author(s)	Quality rating	Participants	Method (*detail of clinical trial*)	Trial willingness	Main reasons cited
1	Trauth, Musa, Sminoff, Jewell & Ricci (2000).	78%	489, Pennsylvania , US.	Random digit telephone survey. Survey measured *willingness to take part in general medical research* and associated factors.	46% willing, 25% not willing, 29% undecided.	*Willing vs. non willing participants* Having a friend or relative with an illness. Being middle aged (35-64 years old). Prior participation in medical research. Favourable attitude towards the use of human subjects. Belief that diverse people participate in research. *Undecided vs. non willing participants* At least college degree. Favourable or neutral attitude towards use of human subjects. Belief that well-being of participants is primary concern of researchers.
2	Carlsson, Merlo, Lindstrom, Ostergren & Lithman (2006).	83%	13,604, Sweden.	*Postal health survey.* Results of responders compared to population register.	58% response rate to the survey.	*Under-representation* Males Individuals with a low level of education Immigrants. Except for immigrants, the under-representation was not large.
3	Williams, Irvine, McGinnis, Murdo & Crombie (2007).	72%	417, Tayside, Scotland, UK	Follow up of older adults who refused to take part in *survey about activities in retirement.* Demographic characteristics and reasons for refusal were collected.	54% refused initial survey. 39% refused follow up study.	*Participation differences* Age (younger>participants) Gender (female>participants) Social class differences (low deprivation= >participants). *Reasons* Male participants less interested in research.

4	Bost (2005)	44%	47 female students, Pittsburgh, US	Questionnaires distributed by faculty members at University to students about participation in a *Health Assessment Program.*	100% refusal to health trial program.	*Barriers* Time constraints. Communication. Fear. Need for program / not beneficial
5	Feveile, Olsen, & Hogh (2007)	83%	4,000, Denmark	*Health related survey* via randomised mailed questionnaires or computer-assisted telephone interviews	58% questionnaires, 56% telephone interviews	*Participation differences in preferred method* Age (31-40 mail, 41-50 telephone) Gender (m=mailed, f=telephone)
6	Spencer, Dawson, Rigby, Leighton & Wakefield (2004)	50%	18, Newcastle-under-Lyme, England, UK	Structured interviews with participants regarding *information sheet on general medical research.*	70% would participate in future research	Greater understanding = greater participation
7	Beebe, Jenkins, Anderson & Davern (2008)	72%	1,636, Minnesota, US	*General health survey* via mail and telephone.	49% participated in survey	*Drivers* Know the organisation conducting research *Barriers* Good health status Busy schedule. Belief surveys are too long
8	Tishler, Apseloff, Batholomae, Reiss, Rhodes & Singh (2007)	78%	28, male, normal healthy volunteers (NHRV's) in phase 1 trial, Minnesota, US	Participants completed Minnesota Multiphasic Personality Inventory-2 (MPMI-2) and a socio-demographic questionnaire during a *drug trial with daily blood sampling.*	N/a	*Reasons* 50% NHRV's showed elevations on at least 1 subscale of the MPMI-2. Discussion suggests NHRV's are 'different' to normal population on personality scales.

9	Kennedy & Burnett (2007)	67%	386/3,302, African Americans, US	Completed questionnaire (Perceptions of Participation in Clinical Research) about *Clinical trials in general*.	20% previous trial participants and 9% of non-participants returned questionnaire	*Drivers* Previous participation Altruism Better / newer treatments Doing something positive for self Helping to prevent / delay disease Free medication / cash *Barriers* Missing work / disruption to routine Arranging child care Side effects of treatment Losing privacy Treated like a 'guinea pig'
10	Dixon-Woods & Tarrant (2009)	78%	26, UK	Healthy volunteer (HV) experience of invitation to participate in *DNA analysis of blood sample regarding Blood pressure regulation.*	N/a	Medical research as public good Risks and safety Organisation and professional credentials Interpersonal trust Visible signs of reasonable practice
11	BeLue, Taylor-Richardson, Lin, Rivera & Grandison (2006)	78%	67 African Americans, US	Focus groups audio taped, transcribed verbatim. Data analysis performed by combining key elements of grounded theory and content analysis. *Perceptions of clinical trials in general.*	N/a	Different themes for males and females. *Males* Business and economics of research Reputation of researchers *Females* Researcher-participant relationship Value of the research
12	Ohmann & Deimling (2004)	72%	225, visitors to Heinrich-Heine University, Germany	Visitors completed structured interviews with regards to socio-demographic variables and attitudes towards *dental, surgical and pharmaceutical clinical trial scenarios*.	89.5% saw clinical trials as important, 25% would participate in a trial	*Drivers* Belief that clinical trials are important General knowledge of clinical trials Previous trial participation *Barriers* Lower participation in surgical trial than dental and pharmaceutical trial scenarios.

Willingness to participate in clinical trials

The measurement of willingness to participate in clinical trials varied across included studies. Studies 1, 4, 6 and 12 [21, 17, 16, 24] reported a percentage of participants who were willing to take part in future (hypothesised) clinical trials, with a median willingness of 25-46%. Studies 2, 3, 5, 7 and 9 [14, 15, 22, 23] reported percentages of participants who had consented to take part in a (actual) clinical trial, with a median of 49-56%. Studies 4, 10 and 11 [17, 19, 12] did not report the number of people who chose not to participate.

Age

Participants in studies included for review ranged in age from 15 to 84 years old. The vast majority of participants were over 18 years old although study 6 included two participants under the age of 16 [16]. Studies 4, 9 and 10 did not report the ages of participants, although they all indicated that participants were over 18 years old [17, 18, 19]. Study 4 reported that the majority of participants were 18-year-old first year university students [17]. Studies 6 (m=38), 8 (m=31) and 11 (male m=32.3, female m=42.7) reported the mean age of participants but made no comparisons with willingness to take part in clinical trials [16, 20, 12].

Studies 1, 2 and 3 found significant correlations between the age of participants and willingness to take part in clinical trials [21, 14, 15]. Younger participants were more likely to participate in study 1. Fifty seven percent of participants aged 18-34 were willing to take part in a clinical trial, in comparison to 49% for the 35-64 age group, 47% for the age 45-64 group and 30% for the over 65 age group [21]. Study 1 also found people aged 35-64 were overrepresented, in comparison to predictions made from statistics about the general population. Study 3 found that younger people were much

more likely to participate in clinical trials than older people [15]. In contrast, study 2 found that younger people were under-represented in a sample of respondents to a postal survey. The response from people under the age of 35 was much less than would be predicted by statistics for the general population (< 35, general population; m = 31.2%, f=29.9%, study population, m = 24.5%, f = 25.5%). The response rates for age groups ranging from 45 to over 65 were representative of the general population [14]. Study 5 found that people in their thirties were significantly more likely to mail their response to a survey as opposed to a telephone interview [22].

Studies 7 and 12 found no relationship between the age of participants and their reported willingness to participate in future clinical trials [23, 24].

Gender

Studies 1 [21] and 7 [23] reported higher percentages of female participants (66% and 51% respectively) and study 10 [19] reported a higher percentage of male participants (55%). Three studies identified gender as a significant factor in response rates. Significantly more females responded to a Swedish public health questionnaire in study 2 [14] than the statistics for the general population would predict (sample f=54.4%, m=45.6%, general population m=50.5%, f=49.5%). Study 5 [22] found that more females than males were willing to respond to mailed questionnaires about health and well-being (m=54.2%, f=62.0%). In contrast, more males than females replied to an invitation to participate in a health research project (m=63%, f=59.7%, study 3). Study 12 found no differences between genders in reported willingness to take part in future trials [24].

Study 11 found different themes between genders in relation to clinical trial participation. Males were more concerned about the business, economics and reputation of research and researchers. In contrast, females were more concerned about the researcher-participant relationship and the value of the research project to the community [12].

Studies 4, 6 and 9 [17, 16, 18] did not publish information about the gender of participants and study 8 [20] had an all male sample. Studies 1, 7 and 10 [21, 23, 19] made no comparisons between the number of males and females approached or differences in their reported willingness.

Educational Level

Three studies found significant correlations between educational level and willingness to participate in clinical trials. Study 1 found that 50% of participants with a college or graduate degree would be willing to take part, as opposed to 44% of participants who had only a high school education [21]. Study 2 found that the representation of people with lower levels of education was lower in the sample than general population statistics would predict (31% to 36%) [14]. Study 7 also found that participants with lower levels of education were significantly less likely to participate in future surveys [23].

In contrast, no differences in educational level were found between participants and non-participants in study 5 [22]. Study 12 [24] also reported educational levels had no bearing on participants willingness to participate in future clinical trials

Social and economic status (SES)

Six studies reported participant's earnings, employment or social status. Sixty percent of the participants in study 8 were unemployed [20]. In study 11, all participants either were in full time education, employment or retired [12]. Studies 8 and 11 [20, 12] did not compare employment or SES with willingness to participate in clinical trials.

Study 1 compared participant's earnings with levels of earnings predicted from census data. A slightly higher representation than expected of people earning $20,000-$40,000 per annum returned surveys. Study 1 also found a significant positive relationship between higher earnings and willingness to participate in clinical trials. Forty two percent of people earning less than $20,000 were willing to participate, in comparison to 52% of people who were earning over $40,000 [21]. Study 3 assigned each participant a 'deprivation level' based upon where they lived. They found that people from areas of high deprivation, in comparison to people from areas of low deprivation, were more likely to refuse to participate in the trial (HD; 62.3% refused, LD; 47.0% refused) [15].

In contrast, studies 7 and 12 found no relationship between employment or occupation, and willingness to participate in future clinical trials [23, 24]. Studies 6, 8 and 11 reported educational levels but made no comparisons with participants' willingness to take part in clinical trials [14, 18, 10]. Study 4 participants' were all students at the same educational level [15]. Studies 3, 9 and 10 did not report educational levels [13, 16, 17].

Finances

Two studies reported that financial incentives were offered to people for participation. Study one and eight paid participants $5 and $75 respectively to complete a survey [21, 20]. Participants in study eight received $3000 to enter phase 1 of a drug trial. Of the

nine studies eligible for review, only studies 8 and 9 mentioned money as a reason to take part in clinical trials [20, 18]. Eighty four percent of participants in study 8 stated that money was a reason for taking part in the clinical trial [20]. Participants in study 9 rated 'getting free medication' as the least important reason for taking part in a clinical trial. However, participants rated the reason 'getting free medication' on average 3.6, in between unsure '3' and agree '4' [18].

Business and compensation were two of the main themes in male focus group discussions in study 12 [24]. Men felt that the research industry is only concerned with making money, "some...research is just for some people (researchers) to make money". One participant suggested that money was not the most important incentive, "don't consider a quick buck, don't give me $100 to be part of a research study that doesn't have to do with bettering …illness" [24].

Altruism

Six studies found altruism to be a key reason for taking part in clinical trials [21, 20, 18, 19, 12, 24]. Study 1 reported that people with a friend or relative with an illness being researched in a trial (58%), were significantly more likely to participate than those who did not (39%) [21]. Participants in study 9 rated 'doing something that will help others' as the greatest incentive for taking part in a clinical trial (Mean score = 4.51, 4 agree, 5 strongly agree) [18].

The authors of study 11 described how the overall value of clinical trials to society was a key theme for females discussing clinical trials in a focus group [12]. The following is a quote used by the authors to illustrate the theme of 'value of research', "If you tell me that researching this will help save millions of lives then I'm more apt to do it than if

it's some rare thing and it might one day help somebody. So if you can make a closer link to how my participating can actually help, I'll be more likely to want to get involved." The authors of study 10 concluded that altruism, or 'medical research as a public good', was a key theme related to people's willingness to take part in clinical trials [19] and concluded that participants' 'are likely to cooperate with a voluntary endeavour *only* if they can produce a moral account of their actions.'

In contrast, only 10% of participants in study 8 reported that 'helping society or a sick person' was a reason for taking part in the clinical trial [20]. Study 12 also found that participants who held the belief that clinical trials helped to improve other people's physical health, were no more willing to take part in clinical trials than those who did not hold this belief [24]. The remaining six studies did not mention altruism as a reason for participation.

Health status

Five studies reported that a person's health status bore little or no relation to their willingness to participate in a clinical trial. Study 1 found no relationship between participants reported willingness to enter a clinical trial and their own health status (in contrast to the health of a friend or relative as mentioned earlier) [21]. Study 2 reported no significant differences in health care utilization costs (medical expenses per person) between people who did or did not participate in a Swedish health survey [14]. Only 3% of participants in study 8 reported that 'helping their own health' was a reason for taking part in the clinical trial. Only two percent of participants in Study 4 reported that the possibility of a clinical trial identifying an unknown health problem was a reason for non-participation [17]. Study 12 found that there was no significant relationship

between willingness to take part in a clinical trial and participants who were, or were not, diagnosed with a chronic disease, or receiving general medical treatment [24].

In contrast to studies 1, 2, 4, 8 and 12, three studies found an association between people's health status and a willingness to participate in clinical trials. Study 7 found a negative relationship between willingness to enter a clinical trial and good health status. People who rated their health status as fair or poor were significantly less likely to take part in future surveys [23]. Study 9 allowed participants to write comments at the end of a survey into 'factors that influence participation'. Eleven participants cited that 'risk to your own health' was a reason for not taking part in clinical trials [18]. Participants over 75 years old in study 3 reported that they were 'too old' to participate. Although they did not specify that this had an impact upon their health, it is possible that 'too old' was related to their perceived health status [15]. Four studies did not mention participant's health as a reason for taking part in clinical trials [22, 16, 12, 19].

Benefits

Studies 1, 4, 8, 9 and 12 examined the relationship between willingness to enter a clinical trial and beliefs about benefiting from participation. All five studies noted that participants did not think that clinical trials participation would be beneficial to them. In Study 1, people who believed that the effectiveness of treatment assigned to participants was 'always the best for the patient' were more willing to participate (47.6%) compared to those who thought that it was 'never the best for the patient' (38.7%). Differences between the groups were not statistically significant, as the vast majority of participants (85%) believed that the treatment assigned 'might be the best for the patient' [21]. Study 9 found similar results when researching different reasons given for taking part in clinical trials. People who stated that they would not be willing to participate were less

likely to agree that the trial would 'help to delay a disease' in comparison to people who were willing to take part [18]. Only 2% of participants in study 4 and 3% in study 8 believed that participation in a health trial would be beneficial for them [20, 17]. Study 12 suggested that there was no difference in willingness to take part in clinical trials between those who believed that participation would, or would not, improve their own physical health [24].

Risk of entering a trial

Studies 1, 3, 4, 7, 9, 10 and 11 described how perceived risks of entering a clinical trial were reasons for not taking part. Study 1 suggested that people's attitudes towards the use of human subjects in clinical trials affected their decision to participate. Fifty two percent of people who favoured the use of human subjects stated that they would be willing to participate, in comparison to 32% of people who did not favour the use of human subjects [21]. People's attitudes regarding the priorities of researchers also seemed to be a reason for participation. Nearly 50% of people who thought the 'well being of participants was more of a priority for researchers than the results of the study' were willing to participate.

Study 9 also found differences in the appraisal of risk for people who had or had not taken part in clinical trials. People who had not taken part in clinical trials (mean=3.46) were more likely to agree that 'experiencing side effects of medication' was a reason for not participating than people who had previously taken part (mean=2.99). Eleven participants also gave feedback at the end of the survey suggesting that 'risks to your health' was a barrier to participation [18].

Studies 3, 7 and 9 identified perceived risks to personal privacy as a reason for not taking part in a clinical trial. Forty-five percent of participants in study 3 did not want a nurse coming to their house and 39% did not want to give away personal details [15]. Study 7 found that privacy concerns were a significant univariate predictor of non-participation in future health surveys [23]. In contrast, non-respondents in study 9 least agreed with 'losing one's privacy' as a drawback to participation [18].

Participants' in study 4 noted specific concerns about the particular clinical trial, with 28% of people stated that the fear of 'getting blood drawn' was a reason for not taking part [17].

Themes regarding risk and safety were prominent in studies 10 and 11. 'Eagerness to serve the public good was tempered by some wariness'. In order to enter a trial, participants must 'feel confident that their decision was not taken irresponsibly or stupidly' [19]. Participants in study 11 were less willing to take part in clinical trials as they thought 'potentially harmful effects of research are often not known by researchers' [12].

Understanding of the research process

Studies 1, 3 and 12 found prior participation in clinical trials significantly increased the likelihood of future trial participation. Study 3 recruited participants from a clinical trial running at the same time [15]. Study 1 described a significant relationship between prior and future clinical trial participation. Fifty five percent of people who had previously taken part in a clinical trial reported that they would be willing to do so again in the future. This is in comparison to the 45% of people willing to participate with no prior experience of clinical trials [21]. Multiple-choice questions assessed knowledge about

the rationale for clinical trials and the research process. Knowledge about the research process, but not the rationale, was significantly correlated with willingness to participate in a clinical trial [21]. Participants in study 12 rated a significantly higher willingness to take part in future clinical trials if they had previously participated (previous participation, m=4.4, no participation, m=1.4, 0-8, 8 very unwilling, $p<0.001$) [24].

Studies 3, 4, 6 and 9 highlighted a lack of understanding of the research process as a barrier to participation. The authors of study 3 [15] concluded that a misunderstanding of the nature and purpose of the trial was one reason for non-participation, based on an analysis of the responses to the open questions at the end of the study. Twenty three percent of participants in study 4 suggested the reason they did not take part in an associated clinical trial was that they 'had not heard about it'. Fifteen percent of the participants also stated that they did not understand the clinical trial [17].

Study 6 evaluated an information leaflet for a clinical trial. The authors suggested that a misunderstanding of the research process could have been a reason for non-participation. Sixty five percent of participants gave a correct explanation of informed consent after reading the leaflet and participants seemed to have problems answering questions on the effectiveness of new treatments versus old treatments [16].

Hearing about the good things that come from a clinical trial (m = 4.36), or an informational meeting about the clinical trial (m = 4.00), were reasons cited in study 9 that people agreed or strongly agreed would help participation [18]. Even though most people agreed with both statements, the informational meeting was the method that people least agreed with and hearing about the good things was the method that most

people agreed with (six methods). Therefore, it might be type of information, rather than amount, which is important [18].

Organisational and professional credentials

Four studies assessed the influence of beliefs about the organisation conducting the trial on a participant's willingness to take part (23, 19, 12, 24). Study 7 reported that an understanding of the organisation conducting the clinical trial was a significant reason for participation. Results suggested that people would be twice as likely to take part in a clinical trial if they knew the sponsor or organisation [23]. Study 12 found no difference in willingness to participate in clinical trials between those people who believed that clinical trials served the pharmaceutical industry's interests, and those who did not [24]. The authors of studies 10 and 11 found the reputation of researchers to be a key theme in interviews regarding clinical trial participation and found that 'visible signs of reasonable practice' were important to participants [19, 12]. These included 'warrants of trust'; such as logos and affiliations with trusted organisations; such as universities and the National Health Service. In comparison, pharmaceutical companies were deemed less trustworthy [19]. Male participants in focus groups were particularly concerned about the reputation of the research facility. Participants' described how they wanted 'a reputable person, an expert, the best doctor and equipment, and a reputable and clean hospital that specialises in the research area' [12].

Relationships with researchers came out as an important theme in the two qualitative studies' exploration of clinical trial participation [19, 12]. Interviews suggested that most participants were able to establish 'swift trust', as interpersonal trust was 'institutionally located'. Participants also commented favourably on encounters, which had characteristics of friendship, respect and politeness [19]. Female participants in

study 11 described how they wanted the researcher to focus on them as a 'human being', to make them feel comfortable, to treat them well and not as though they were guinea pigs' [12].

Time constraints and perceived burden

Four of the studies eligible for review reported time constraints or the burden of participation as a reason for not taking part in a clinical trial. Attitudes about not having enough time, or being burdened by participation, were both significantly correlated with the decision not to participate in future clinical trials in study 7 [23]. Having too many other commitments and not enough time to take part in clinical trials were also reported as reason in open-ended questions in studies 3 and 9 [15, 18]. Fifty eight percent of participants in Study 4 also supported these findings suggesting that they were too busy to take part in a clinical trial [17].

Personal Interest

Studies 3, 4 and 7 specifically asked people about their interest in clinical trials. Thirty one percent of participants in study 3 said they were not interested in the clinical trial and 27% said that they were not interested in research in general. More men (33%) than women (22%) reported being disinterested in clinical trials [15]. Fifteen percent of participants in Study 4 also reported disinterest in clinical trials as a reason for non-participation [17]. Study 7 identified the saliency of a study as a reason for participation, with 92% of participations reporting that they would take part in a clinical trial if it 'strongly' or 'somewhat' interested them. However, regression models employed by the study suggested saliency was not a significant predictor of future trial participation [23]. Nine people responding to an open-ended question in study nine said that an interest in 'learning about medicine and the body' was a reason for taking part in

clinical trials [18]. Study 1 found people who agreed that diverse types of people participated in clinical trials, were significantly more likely to take part in future trials than those who did not [21].

Personality

Only study 9 looked at personality traits as a factor that could influence participation in clinical trials. The authors of study 8 conducted a personality assessment (MMPI-2 [13]) on participants of a pre-running clinical trial. No relationships were found between personality subscales and clinical trial participation. However, 50% of participants had elevated scores on a variety of subscales of the test. The authors were unable to draw firm conclusions from the results but suggested clinical trial participants might vary in personality traits, in comparison to the public [20].

Reasons to participate in clinical trials (non-clinical sample) reported in this review are summarised in Table 4.

Quality of included articles

The maximum score achievable on the quantitative quality assurance checklist was 18 (Appendix 5). Criteria were rated on a dichotomous Y (1) / N (0) scale. The mean overall quality rating was 12.6 with a range of 8 – 15 criteria met. Poorly scored items (<8) on the whole included; description of sample characteristics; clear description of principal confounders; description of the characteristics of sample lost to follow up; representativeness of recruitment population; representativeness of the participant population; control or adjustment for different lengths of follow up; reliability and validity of outcome measures; and sufficient power to detect a significant effect. Included in all of the quantitative articles (n=10) were; the objective of the study; a

description of the main outcomes in the method; a description of the main findings; representative staff, places and facilities; clear description of 'data dredging' where applicable; appropriate statistical tests; and cases and controls were recruited at the same time where applicable.

The maximum achievable score on the qualitative quality assurance checklist was 18 (Appendix 7). Both articles provided analysis next to relevant extracts from transcripts and both scored 14/18. Study 11 compared three previous qualitative studies and therefore scored poorly on items regarding the initial coding of data. Study 10 scored poorly on items relating to the discussion of results generalisability and diversity of accounts.

Two Trainee Clinical Psychologists assessed the quality of seven quantitative articles (Appendix 6) and one qualitative article (Appendix 7). Items on the quantitative quality assurance checklist had an average inter-rater reliability score of K=0.83. [3]

[3] Kappa Statistic

Table 4. Reasons for (not) participating in clinical trials from non-clinical populations

Reason	Study findings
Demographic factors	
Age	S1: Younger participants were more willing to enter clinical trial. 35-64 over represented in comparison to prediction from population statistics. S2: Participants <35 were underrepresented in study in comparison to population statistics. S3: Older participants (>75) correlated to belief 'too old to enter clinical trial'. S5: Participants aged 30-39 more willing to respond via post vs. telephone. S7 & 12: No effect of age.
Gender	S1&7: Higher % female participants. S3&10: Higher % male participants. S2: Lower % male responders than predicted by population statistics. S5: Greater % female willingness to respond to postal questionnaire. S12: No significant differences in gender willingness. S11: Different themes for males and females.
Educational level	S1: Higher education = greater willingness. S2: Less lower educated participants than expected from population statistics. S7: Lower educated participants were significantly less willingness to participate. S5&12: No differences between participants with different educational levels.
Social and economic status	S1: $20,000-$40,000 over represented in respondents. Greater earnings = greater willingness to enter trial. S3: Participants from high deprivation areas were less likely to enter clinical trial. S7&12: No difference between employment / occupation and willingness.
Participant characteristics	
Personality	Study9: No personality scale predictors. 50% participants had elevated scores on different MMPI-2 subscales.
Health status	S1,2,4,8&12: No association between health status and trial participation or willingness S7: Good health status = less willing to enter clinical trial.
Practical issues	
Time constraints and perceived burden	S3&9: Participants reported 'too many other commitments' and 'not enough time' to enter a trial. S7: Attitude of 'not enough time' or 'burden by participation' correlated with non-participation. S4: 58% participants reported being 'too busy' to enter clinical trial.

Organisation and professional relationships and credentials	S7: Understanding of the organisation conducting trial had significant influence on participation. S10&11: Reputation of organisation and researchers key theme related to trial participation. More trust in relationships with researchers affiliated with trusted organisations. S11: Being treated as a human being and not 'guinea pig' was a key theme in trial participation. S12: No differences between participants that did and did not think trials serve the pharmaceutical industry's interests.
Understanding of the research process	S1, 3&12: Prior trial participation predicted entering a future trial. S3, 4, 6 &9: Lack of understanding of research process, purpose and rational was a significant barrier to participation.
Reasons for participation	
Altruism (helping others)	S1: Participants with a friend or relative with illness studied were significantly more willing to enter trial than those who did not. S9: 'Doing something to help others' was rated the greatest incentive to enter trial. S11: The overall value of clinical trials to society was a key theme regarding trial participation. S10: 'Medical research as public good' was a key theme regarding trial participation. S8: Only 10% stated 'helping society or sick person' was a reason to enter trial. S12: Belief trials improve health for others were not related to willingness to enter clinical trial.
Benefits	S1, 4, 8, 9 &12: Participants stated no benefits to taking part in clinical trials.
Finance	S8: 84% participants stated money was a reason for participation. S9: Free medication rated as least important reason.
Personal interest	S3: 31% not interested in research (significantly more men not interested). S4: 15% not interested in research. S7: 92% participants would participate in trial if it 'strongly' or 'somewhat' interested them. S9: 9 participants described 'learning about medicine and the body' as reason to enter clinical trial.
Reasons for non-participation	
Risk of entering a trial	S1, 3, 4, 7, 9, 10 & 11: Risks of entering a clinical trial were reasons not to enter clinical trial (risk to health, privacy, side effects).

Discussion

Decision making model

The review suggested that similar to patients [5], non-clinical participants assess a 'personal balance account' before consenting to take part in a clinical trial. Participants appear to weigh up reasons to enter a trial such as altruism and personal interest, with reasons not to participate such as risks, time constraints and perceived burden. Organisational credentials, relationships with professionals and an understanding of the research process also affected the decision to participate, as with patients. Similarly, background factors such as age, gender, educational level and SES were found to influence the decision making process.

Differences between clinical and non-clinical sample reasons to participate in clinical trials were also apparent. Health statuses of non-clinical populations did not appear to influence the decision making process as significantly as reported for patients [5]. Altruism and personal interest were reported as reasons to take part in clinical trials so it seems likely that these are important factors for patients. However, in the absence of benefits afforded to patients such as improved or different treatments, it is likely that altruism and personal interest are more significant for non-clinical populations in the decision making process.

Correlations between willingness to participate and demographic factors often contradicted each other across the studies reviewed. In general, a greater number of studies suggested that participants, who were younger [21, 15], female [14, 21, 22, 23], highly educated [14, 21, 23] and from areas of low deprivation [15, 21] were more willing to take part in clinical trials. Males and females had different reasons for participating in clinical trials [12], reflecting an influence of gender on beliefs about

clinical trials. Further research would enable a richer understanding of how gender influences willingness to enter a clinical trial. Participants with lower educational levels may view clinical trials as an arduous academic exercise, especially long mailed questionnaires. In contrast, highly educated researchers or professionals undertaking clinical trials are more likely to have an interest, or be aware of, clinical research. Reasons for trial participation appear to vary across demographic groups and 'one size fits all' recruitment strategies may 'at best be inefficient and at worst inappropriate' [15, 14].

Personality subscales on the MMPI-2 were not significantly related to clinical trial participation [20]. Rather than suggest that personality factors are not related, it is more likely that the MMPI-2 did not assess specific personality traits related to trial participation, (e.g. altruism). It seems that consistent with patient groups, background factors influence how non-clinical participants weigh up, and assign significance to, the 'pros and cons' of participation.

Perceived risks associated with clinical trials were the most cited barrier to participation [12, 17, 18, 19, 21, 23]. Concerns about risks 'unknown to researchers' [12] are consistent with previous findings suggesting participants have a much stronger belief in the existence of 'unknown effects', than experts [26]. Perceptions of risk do not always correlate with measurable probabilities of risk, suggesting other factors influence risk perceptions [25]. Participants are significantly more inclined to participate in clinical trials if they trust the researcher, or respect the organisation conducting a trial [12, 19, 23]. The findings are consistent with idea that in the absence of control over a perceived risk, its significance is dependent upon beliefs about the existence and reliability of risk management procedures [27]. Trusting the researcher and the organisation conducting

the trial may help reduce fears about entering a trial and potentially tip the 'personal balance account' towards participation.

Not having enough time, feeling burdened and having a poor understanding of clinical trials are common barriers to clinical trial participation [17, 18, 23]. However, trial participants are much more likely to enter a future trial than people who have never participated [18, 21]. Although this could reflect individual preferences, trial participation may modify negative assumptions about clinical trials. Perceptions of clinical trials are likely to be anchored by particular heuristics, such as the availability of media reports of risks from trial participation, or representations of medical procedures.

Altruism, benefits and personal interest were described by reviewed studies as reasons to participate in a clinical trial, for a non-clinical population. The authors of the two qualitative studies included in the review described motivations such as 'helping society' and displaying 'moral character' as important reasons for trial participation [18, 19, 21]. Further research is needed for a more detailed understanding of the relationship between altruism and trial participation, such as how individual trials trigger an altruistic reaction in potential participants. It seems that altruism and personal interest are prominent reasons to take part in a clinical trial for people from a non-clinical sample, as nearly all studies found participants associated taking part in a clinical trial with few or no benefits [12, 15, 17, 18, 19, 20, 21, 23].

Financial incentives were only reported to be a significant reason to enter a clinical trial in one reviewed study (study 8). The low frequency reporting of financial drivers for clinical trial participation is surprising and inconsistent with previous commentaries,

which suggest money may be one, or even the main, reason for trial participation in a non-clinical sample [28]. Money can 'attract subjects to research and overcome inertia and other barriers' [28], which is consistent with the decision making model. The majority of included studies employed low risk methodologies (e.g. surveys); therefore, it may be that financial incentives were not considered necessary in relation to perceived barriers. In contrast, participants in study eight were recruited from a potentially risky drug trial that lasted 30 days. Participants were given $3000 to enter the drug trial and 84% suggested money was the main reason for participation. Hence, financial incentives seemed to outweigh the perceived barriers to trial participation.

Recommendations for services

The findings of this review have implications concerning services and practice of key practitioners. However, a 'one size fits all' strategy of recruitment is suggested to be inappropriate [15]. Considerations concerning the sample population may help to ensure efficient, effective and representative recruitment. This could include tailoring the language of information to the educational level of participants, or stressing particular factors found to be relevant to certain age groups or genders.

Attitudes towards clinical trials and the appraisal of risk are important reasons in the decision to take part. Therefore, researchers should attempt to communicate the realistic risks to health and privacy to dispel potential unfounded anxieties about clinical trials. Concerns about trial participation are often idiosyncratic and discussing the spectrum of these may increase people's negative perceptions of risks associated with participation. Therefore, an individualised recruitment system using individuals' preferred methods, such as post, email or telephone, is likely to increase recruitment. It seems a balance needs to be struck between tailoring information to individuals' preference and

satisfying requirements of regional ethics committees. Non-clinical participants rarely see benefits to clinical trials. Therefore, individualised benefits such as financial incentives, providing interesting findings and helping society could be stressed.

Making communications more idiosyncratic may not only help to tailor information to particular groups of people, it may also help to increase people's perceptions of how important their participation is. A more individualised approach may increase empathy towards the researcher or research topic and in turn promote altruistic behaviour(s).

An understanding of clinical trials (including; participants' exact involvement in the research process; why the trial is being conducted; the 'good things' that have / will come from the particular trial; an association with a well known and respected sponsor of clinical trials) was highlighted in the review as an essential factor in trial recruitment. Advertising and providing accessible information about clinical trials is likely to bolster recruitment.

Limitations of the review

Median recruitment levels (49%-56%) and willingness to participate (25%-46%) in clinical trials could not be compared to patient samples due to a paucity of literature on average recruitment levels. Direct comparisons of studies may also be invalid due to the diversity of clinical trials and associated idiosyncratic reasons for participation. Quality assessments suggested some study samples were not representative of a general non-clinical population (e.g. sampled only previous trial participants). Ratings of willingness may therefore have been an artefact of the methodologies used. Future research could attempt to review the general populations' attitudes towards clinical trial participation.

The review compared clinical trials with a wide variety of methodologies, therefore reasons to participate for a postal survey may not have generalised to studies with an invasive medical procedure.

Many of the included studies did not assess for important principal confounders such as religious beliefs and / or beliefs about human medical testing. The samples of participants used in the studies were often not representative of the general population. Very few studies reported measures' reliability and validity information and the majority of studies did not assess for the characteristics of non-respondents.

Ideas for future research

It is for future researchers to evaluate the effectiveness of the recommendations made for clinical trial recruitment strategies. The review identified a variety of reasons that influence the decision to take part in a clinical trial and presented a decision making model for a non-clinical sample. Further research should aim to provide a deeper qualitative understanding of how complex inter-relationships between reasons influence willingness to participate in clinical trials. Further quantitative research could also evaluate the influence of these reasons identified in different types of trials.

Conclusions

Reasons for participation in clinical trials from a non-clinical sample were systematically reviewed. Similarities and differences between patient groups were described and reasons for (non) participation were mapped onto a pre-existing decision making model [5]. Recommendations were made for future recruitment strategies and further research.

List of abbreviations

NHS – National Health Service

CINAHL – Cumulative Index to Nursing and Allied Health Literature

MEDLINE – U.S. National Library of Medicine's® (NLM) premier bibliographic database

MPMI-2 – Minnesota Multiphasic Personality Inventory-2

Declaration of interests

The author had no competing interests.

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PART TWO:

Male reproductive health:

Reasons why men may choose to participate in trials

This paper was written in accordance with guidance for authors from the journal of 'Human Reproduction' (Appendix 8).

Male reproductive health research: reasons why men may choose to participate in trials

Abstract

BACKGROUND: Male reproductive health trials (RHTs) are often under-resourced. Study 1 aimed to determine drivers and barriers to participation, and to test for the significance of demographic factors, masculinity and altruism, on willingness to take part in a PES (pre-ejaculatory fluid study). Study 2 aimed to qualitatively explore men's reasons for participating in a PES. **METHOD: S**tudy 1: 505 men from around the world completed an online survey, which included demographics, perceived masculinity questionnaire (MQ), self-report altruism scale (AQ), and reported willingness to participate in a PES. Participants also commented on drivers, barriers, and the impact of masculinity on their reported willingness. Study 2: Five men completed a semi-structured interview about their experience of participating in a PES, and the drivers and barriers to participation. Interviews were transcribed and analysed using interpretive phenomenological analysis. **RESULTS:** Ordinal regression showed that altruism, socio-cultural roles, age, number of children, relationship status and continent of origin were significantly related to willingness to participate in a PES. Qualitative comments in study 1 reported practical concerns as the most common barrier to PES participation. Beliefs about the influence of masculinity varied. In study 2, three main themes emerged; conflict in decision making between doing a 'good thing' and the shame associated with a 'socially frowned upon' act; performance anxiety, feeling 'less of a man' and 'inadequate'; and humour and other strategies to cope with difficult feelings. **CONCLUSION:** Potential and actual participants would appear to weigh up pros and cons of RHT participation. The significance of pros and cons appeared to be idiosyncratic and influenced by background factors. Recommendations for services and further research are made.

Introduction

Rationale

The World Health Organisation (WHO) defines reproductive health (RH) as a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity (WHO, 2010a). RH addresses reproductive processes, functions and systems at all stages of life. RH therefore implies that people are able to have a responsible, satisfying and safe sex life and that they have the capability to reproduce and the freedom to decide if, when and how often to do so (WHO, 2010a). Reproductive and sexual ill heath accounts for 12% of the global burden of ill health for men (WHO, 2010b). Therefore, RH problems cause physical, mental and social well-being difficulties for a large number of men around the world. The scale of problems caused by male reproductive ill health illustrates the importance of research in the area.

Clinical trials are essential for researchers to provide an evidence base for practice in the field of RH. 'Doctors, other health professionals and patients need evidence from clinical trials to know which treatments work best. Without this evidence, there is a risk that people could be given treatments that have no advantage, that waste NHS resources and that might even be harmful' (National Health Service, 2010). Researchers need to recruit both participants from RH and reproductive ill health populations, in order to carry out these trials.

However, participation rates for males in RH clinical trials are often very low (Muller, Rocherbrochard, Labbe-Decleves, Jouannet, Bujan, Mieusset, et al, 2004). Studies reporting participation rates suggest that semen collection rates range between 13% and 19% (Muller, et al., 2004). This is unsurprising as men seek infertility treatment less often than women and are reported to be less committed to the treatment process

(McGrade & Tolor, 1981). Low participation in RH treatment is paralleled with findings that suggest men as a group seek professional help much less frequently than women for a range of health problems, including depression, substance abuse and physical disability (Addis & Mahalik, 2003). The National Institute for Clinical Excellence (NICE, 2008) recommends that research should be commissioned to 'establish the link between effective approaches to community engagement and longer-term health outcomes'. NICE (2008) also specifically recommends that research should 'describe the theoretical links between the context, process, structure and impact of the activity'. Research into the area of male RH trial recruitment is therefore needed (Muller, et al., 2004) and recommended (NICE, 2008).

Male reproductive health trial (RHT) participation research

Very few studies have been published on factors that influence a man's decision to take part in a reproductive health trial. Muller, et al, (2004) compared the characteristics of the partners of pregnant women for three levels of participation: completion of a refusal form, completion of the study questionnaire only, and agreement to complete the study questionnaire and give a semen sample. Men who completed the study questionnaire tended to be younger and better educated than those who did not. Participants who completed the study questionnaire and gave a semen sample were more likely to have experienced RH problems in their family than those who only completed the study questionnaire.

Cultural differences in relation to participation were also found (Muller, et al., 2004). Participants in France, comprising of a large African community, were described as less likely to participate as semen collection is seen as taboo. There are problems with extrapolating the study's findings to the UK National Health Service as the study was

conducted in France. The study was also limited to partners of pregnant women, therefore not representing single men and men without children.

There has been more research into the drivers and barriers of semen donation. There are different factors that influence men's willingness to participate in RHTs and donate semen. Daniels, Curson and Lewis (1996a) suggested that personal circumstance, laws of anonymity and laws regarding potential recipients all influenced a man's decision to donate semen. Altruism[4] is reported to be the predominant motivation for semen donation (Handelsman, Dunn, Conway, Boylan, & Jansen, 1985). Motivation to donate semen has also been found to increase if attention has been brought to RH because of sterility among a man's relatives (Lalos, Daniels, Gottlieb, & Lalos, 2003). Edelmann (1996) described how different studies have found different typical donor types. One study found the typical donor was aged 41 and was not intent on having any more children, while another study found that the typical donor was aged 23 and had not been in any steady relationships.

A systematic review of published literature from 2000 until 2010 also suggested that age, education, gender and altruism were factors associated with willingness to take part in clinical trials in general, for a non-clinical sample (Sanderson, in preparation). The review suggested that men who were younger (Trauth, Musa, Siminoff, Jewell & Ricci, 2000; Williams, Irvine, McGinnis, Murdo & Crombie, 2007) and had higher levels of education (Trauth, et al, 2000; Carlsson, Merlo, Lindstrom, Ostergren, & Lithman, 2006; Beebe, Jenkins, Anderson, & Davern, 2008) were more willing to take part in a clinical trial.

[4] A voluntary effort to benefit a recipient, with no expectation of reward.

Gender differences have been found in clinical trial participation. An analysis of responders to a postal public health questionnaire survey in Sweden suggested that there was a significantly higher ratio of female to male responders than would be expected from population statistics (f=54.4%, m=45.6%) (Carlsson, Merlo, Lindstrom, Ostergren, & Lithman, 2006). Feveile, Olsen & Hogh (2007) also found that significantly more females than males responded to both a postal and telephone health survey in Denmark (m=54.2%, f=62.0%).

Masculinity

A gender difference in participation in RHTs suggests that being a man, or masculinity[5], is potentially a relevant factor when assessing the drivers and barriers to participation. Social constructionist theory suggests that masculinity is defined by people and their context (Moynihan, 1998). Courtenay, McCreary & Merighi (2002) describe how health related beliefs and behaviours are ways of demonstrating femininities and masculinities, in the same way as language and sports. Courtenay et al, (2000) suggest that to demonstrate masculinity entails behaviours that undermine ones health.

Independence, self reliance, strength, robustness and toughness are masculine stereotypes (Golombok & Fivush, 1994). Gender stereotypes can provide 'collective, organised and dichotomous' meanings of gender and often become widely shared beliefs about who women and men innately are (Pleck, 1987). Males are encouraged to conform to these stereotypes by society (Bohan, 1993) and this then reinforces self-fulfilling prophecies of such behaviour (Crawford, 1995). Health behaviours may be one of the practices through which masculinities (male and female) are differentiated from one another (Messerschmidt, 1993).

[5] The qualities which are considered to be typical of men

Inhorn (2004) explored the connection between masculinity and the emphasis put on different aspects of health, for example greater emphasis on muscle mass than illness. She concluded that disorders such as infertility and erectile dysfunction are seen as particularly emasculating. In a similar finding, Dixon-Mueller (1993) found that sexual behaviours play a key role in defining gender roles and identities. There are also gender differences in experiencing infertility. Women often perceive it as a devastating stigma[6] that jeopardises their sense of being a 'complete' woman (Whiteford & Gonzalez, 1995). Men on the other hand often experience infertility as a threat to masculinity and sexual potency (Webb & Daniluk, 1999).

Moynihan (1998) describes a dynamic element between gender and health care professionals. Masculinity is 'not what we are, but what we do in social situations' (Moynihan, 1998). Doctors often refer to men's bodies with mechanical analogies (therefore reinforcing this belief), for example, a man who has lost a testicle to cancer may be told that 'one cylinder is as good as two.' Moynihan proposes that by looking at gender rather than biological sex, from a constructionist point of view, practical changes can be made in the doctor-patient relationship and highlight problem areas in medical practices / research that need further investigation.

Altruism

As previously mentioned, altruism has also been found to influence clinical trial participation. People with a friend or relative with an illness researched in a clinical trial were significantly more likely to participate than those who did not (58%:39%: Trauth,

[6] Characteristics or activities that society considers to be deviant or distasteful

et al, 2000). ‘Doing something that will help others’ was reported by participants as the greatest incentive for taking part in a clinical trial (Kennedy & Burnett, 2007).

Research suggests that altruism is an influential factor in the decision to take part in clinical trials (Sanderson, in preparation) and donate semen (Handelsman, Dunn, Conway, Boylan, & Jansen, 1985). It is therefore likely that altruism also influences a man’s decision to take part in a RHT. Philosophically the identification of truly altruistic behaviour has been questioned. Lawler and Thye (1999) propose that the decision to engage in helping behaviours is based on a social exchange; people try to maximise the ratio of social rewards to social costs. Similarly, Eisenberg and Fabes (1991) suggest that altruistic behaviours are often an attempt to relieve personal distress; such as arousal and disturbance caused by seeing somebody in distress. The empathy-altruism hypothesis states that people with higher levels of empathy are more likely to engage in altruistic behaviours (Bateson, 1991).

Sociobiologists have argued that altruism is a method of ensuring the continuation of one’s genes, by helping one’s children or kin group (Wilson, 1978). Wilson (1978) suggests that altruism is genetically coded differently for males and females: Women, who arguably have limited and recognisable genetic interests, tend to display altruism more readily within the family. In comparison, men have the potential to reproduce on a much wider scale and therefore have a greater interest in contributing to the well being of the wider system.

Pandey and Griffitt (2006) have disputed the evolutionary perspective on gender differences. They concluded that depending on the methodology, some studies have shown that males demonstrate a higher degree of displayed helpfulness, while other

studies have suggested that women have greater altruistic tendencies. Eagly and Crowley (1986) argue that sex differences in the expression of altruism could be due to gender-defined roles. For example, females are often socialised to avoid engaging in high-risk behaviours, which are often required for what society deems as altruistic behaviour. Dougherty, (1983) described how the elicitation of altruistic behaviour is affected by the sex-role appropriateness or inappropriateness of the requester. In summary, a study examining impact of research assistant gender found that the male expert and female non-expert recruited the most participants. Dougherty (1983) concluded that higher recruitment levels were due to the perceived appropriateness of sex-roles.

In summary, the literature suggests that demographic factors (age, education, ethnicity, relationship status & number of children), masculinity and altruism influence participation in clinical trials and semen donation. It has also been suggested that altruism can be modulated by gender differences (Wilson, 1978; Pandey & Griffitt, 2006; Ullian, 1984; Dougherty, 1983). Therefore, it is reasonable to suggest that demographics, altruism and masculinity not only influence a man's decision to take part in a RHT, but also influence each other. To date there has been no empirical research into the relationship between these factors and willingness to participate in RHT. A greater understanding of the influence of these factors could guide future research into strategies to improve recruitment into male RHTs.

Aim of study one

To assess the relationship between Masculinity and Altruism scores (Independent variable) and ratings of willingness to participate in a RHT (Dependent variable). To record and control for demographic information.

The secondary aim was to collect participants' subjective opinions about drivers / barriers and perceived impact of masculinity on their willingness to participate in a RHT.

Hypotheses

1. The higher the score on the Masculinity Scale, the less willingness there will be to participate in the RHT.
2. The higher the score on the Altruism Scale, the greater the willingness there will be to participate in the RHT.

Method

Recruitment

The local Post Graduate Medical Institute Ethics Board granted ethical approval for the study in March 2009 (Appendix 9). Participants were recruited via advertisements placed on emails to Post Graduate Students at the local university, a male health message board (MSN) and a social networking website (Facebook, 2009 to 2010). The advertisement showed a woman holding a board quoting 'Are you man enough?' and gave a brief summary of the study (Appendix 10). Information about the study accompanied email and message board advertisements (Appendix 11). When clicked upon, the advertisement directed participants to an online survey. Survey information was presented and participants were asked to indicate their consent to take part

(Appendix 12). To be eligible for the study, participants had to confirm that they were male and over 18.

Measures

The survey consisted of 65 questions, including demographics, masculinity, altruism, willingness to participate in a reproductive health trial, and the barriers / drivers to participating in a reproductive health trial (Appendix 13).

Masculinity was measured using the Perceived Masculinity Questionnaire (MQ: Chesebro & Fuse, 2001). It was created after reviewing literature on the beliefs and behaviours that construct the concept of masculinity in Western society. It comprises 10 dimensions including; physiological energy, physical characteristics, gender-related socio cultural roles, subjective gender-identity, gender-related age identity, gender-related racial and national identities, idealized masculinity, sexual preference, lust and male eroticism (Appendix 14[7]). Internal consistency of all MQ subscales had a Cronbach's alpha of 0.68. Criterion validity was tested by calculating that males scored significantly higher than females on all subscales apart from 'gender related age identity' and 'gender related racial and national identities.'

The Self Report Altruism Scale (AQ: Rushden, Chrisjohn, & Fekken, 1981) consists of 20 items measuring altruistic actions that benefit strangers and organisations. Rushden, Chrisjohn & Fekken (1981) assessed the validity of the AQ by correlating scores with peer ratings of altruism. Peer ratings had an internal consistency Cronbach alpha of 0.89, (N=416) and had a significant positive correlation with the AQ, r (86) = 0.35, (P <0.001). The predictive validity of the AQ was tested by correlating results with eight

[7] Description of each dimension on the MQ

'altruistic' responses, for example volunteering. The AQ positively and significantly related to 4/8 measures and was found to predict a linear combination of the eight measures, $r = 0.40$ ($P < 0.01$).

Procedure

After giving informed consent (ticking agreement to complete survey), participants were required to select their age (18–27, 28-37, 38-47, 48-57, 58+), educational attainment (SAT's, GCSE's, NVQ, Vocational Course, A Levels, University Graduate, Post Graduate), country/ continent of origin (United Kingdom, Europe, Africa, Asia, Americas, Australasia), ethnicity (White, Mixed, Asian, Black, Other), relationship status (Single, Long Term Relationship, Married, Divorced, Widowed), and number of children (0, 1, 2, 3+) from a set of multiple choice tick boxes.

Participants were then required indicate their response on a 7-point Likert Scale for each question of the MQ and a 5-point Likert Scale for each question of the AQ. Parameters of the MQ were dependent on the nature of the question, for example, parameters 'strongly desirable' to 'strongly undesirable' were used for questions about the desirability of certain masculine traits. Parameters of the AQ Likert Scale assessed the frequency of altruistic behaviours (e.g. donated blood), from 'never' to 'always' / 'very often'.

A poster advertisement (Appendix 13) for a trial investigating 'pre-ejaculatory fluid' (PES) was presented to participants. It required men to give a semen sample to help answer questions about fertility and condom use. The advertisement offered participants a personal sperm count and £10 expenses. A 5-point Likert scale then asked participants to hypothetically rate their interest in taking part in the study. Participants were

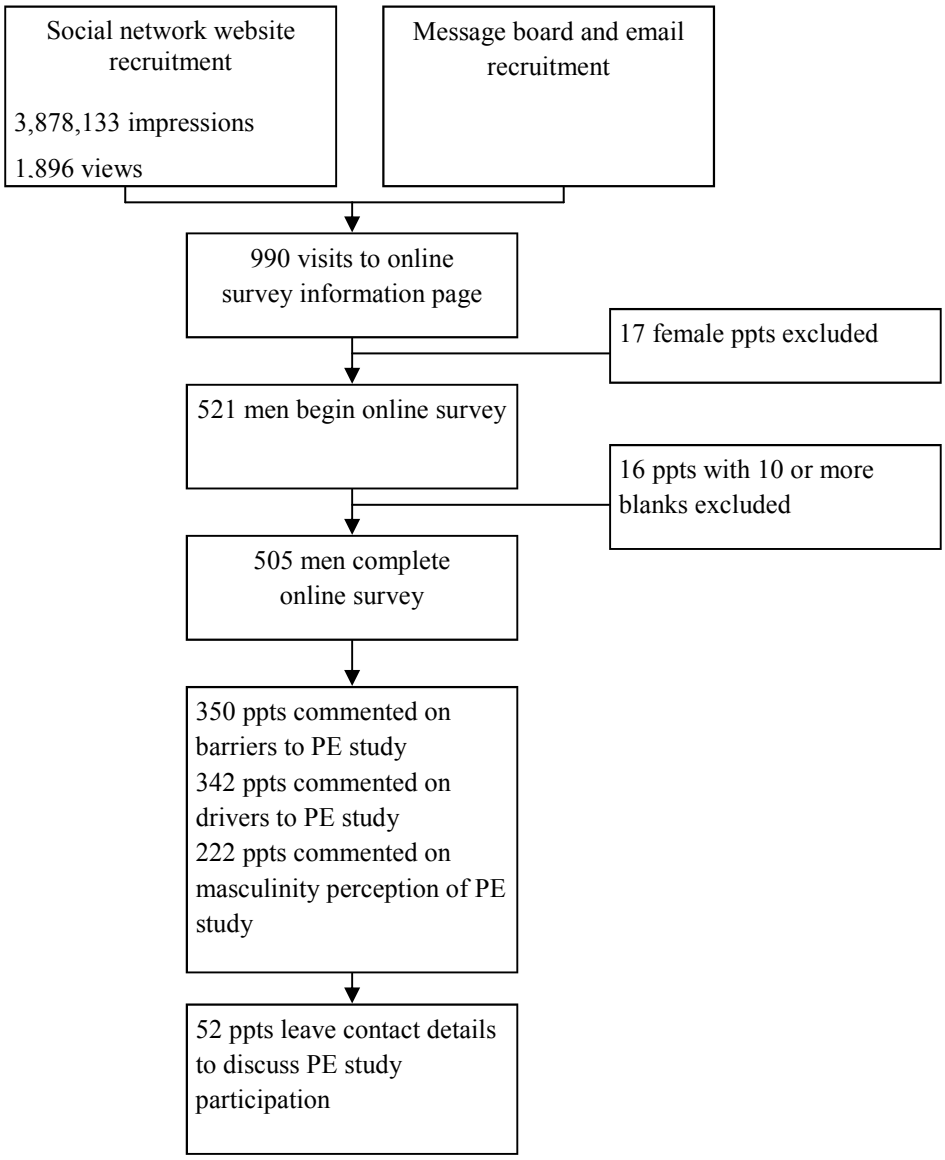
instructed to rate their willingness to take part in the PES, if it was located in their area. The scale ranged from 1; 'not interested at all' to 5; 'very interested'. The PES paper is currently in submission (Killick, Leary, Trussell, & Guthrie).

Comment boxes asked for reasons for and against PES participation. Survey respondents were also asked to comment on how masculine they perceived participating in the PES to be. The final question asked participants to leave their contact details if they would be willing to discuss their experience of taking part in the PES. Results of interviews are discussed in study 2.

Participants

The recruitment process is described in figure I. Between March 2009 and March 2010, 3,878,133 impressions of the advertisement were presented on Facebook (Facebook, 2009 to 2010) and it was clicked on 1,896 times (0.049% of the total impressions). Statistical data regarding recruitment is not available for emails or message board advertisement (MSN). People who received an email were invited to forward the email to male contacts who they believed might be interested in participating in the online survey. The information page was viewed by 990 people. Seventeen participants were excluded as they stated that they were female. A total of 521 men completed the survey. Sixteen participants were removed due to recording 10 or more blanks on the questionnaire, leaving 505 participants. Three hundred and fifty participants left comments for reasons not to participate (in the PES), 342 left reasons to participate (in the PES), and 222 left comments about how masculine the advertised PES was deemed to be. Fifty-two participants reported contact details, implying a willingness to participate in, and discuss, their experience of the PES.

Figure I[8]. Participant recruitment process



Sample size requirements and analysis procedure

An ordinal regression was used to test the significance of relationships between the dependent variable (willingness to participate) and independent variables (subscales on the masculinity and altruism scales). The analysis adjusted for amalgamated categorical demographic co–variables such as educational level and age. Distributions of responses for the five categories of the dependent variable were not easily predicted. There may

[8] Roman numerals used due to author guidelines for 'Human Reproduction'

have been a 20% response for each of the five categories on the Likert scale outcome, or there may have been a much more skewed distribution (previous research has reported low rates of willingness to participate in RHTs; Muller, et al., 2004). In the latter case, the study would have needed a much larger sample size for adequate statistical power when modelling predictors than in the former case. However, based on sample sizes typically used in log-linear modelling of categorical data, a sample size target of 500 was set. One-way analysis of variance and Spearman's rho correlations checked for differences and correlations between demographic factors and variables of masculinity and altruism.

Participants' comments about barriers, drivers and perceived masculinity of participation in the PE study were coded, and frequencies counted. This procedure was also independently undertaken by a Trainee Clinical Psychologist and results compared. Results revealed thirteen differences in coding (7 barriers, 2 drivers & 4 perceived masculinity), which were discussed and re-coded after agreement.

Results

Descriptive Statistics

Participants were grouped according to demographics and the following groups were collapsed for the purpose of analysis; UK and Europe; Africa and Asia; 58 – 67 and 67+; and Divorced or Widowed. The highest percentage of participants were aged 18 – 27 (57.4%), from Europe (44.7%), white (86.0%), university graduates (30.7%), single (47.2%) and had no children (70.2%). Demographic characteristics of participants are shown in Tables III to VIII.

Masculinity

The mean total score on the MQ was 198 (SD=21) with a range from 138 to 245. According to Cheesebro & Fuse (2001), the mean was in the 'average masculinity group' (186-225) and was slightly lower than an average score of 205 (Appendix 14). Table I shows the descriptive statistics for the individual subscales of the MQ. Subscale scores were similar to normative data (within one standard deviation of the mean) provided by Cheesbro & Fuse (2001) (Appendix 14). Results suggest that average masculinity scores were slightly lower in comparison to normative data from a US sample (N=331), although differences were not significant.

Table I. MQ subscale descriptive statistics.

MQ Subscale	Mean	SD	Min score	Max Score	N*
Physiological Energy	17.6	4.5	4	28	497
Physical Characteristics	18.0	3.3	6	28	503
Socio-Cultural Roles	13.5	7.9	4	28	500
Idealized Gender	22.1	3.5	10	28	494
Sexual Preference	24.6	4.6	6	28	496
Subjective Identity	20.3	4.5	4	28	495
Age Identity	24.5	3.8	4	28	495
National Identity	25.2	4.7	8	28	496
Lust	13.0	3.6	4	24	499
Male Eroticism	19.7	4.1	4	28	493

*N Number of participants who answered all questions on the subscale

Altruism

Forty-two participants' scores on the AQ were removed due to missing data leaving 463 valid responses. Mean score was 46 (SD=11) with a range from 20 to 75. Mean altruism score was 9 points lower than results from five samples (M=55, range=52-57, SD=11) published by Rushden, Roland & Fekken (1981), which indicates that the sample was (on average) less altruistic than students from the US.

Willingness to participate in the pre-ejaculatory fluid study (PES)

Table II reports frequencies and percentages for each rating of willingness to participate in the PES. All 505 participants completed the willingness question as participants who did not answer the question were excluded during preliminary analysis of results.

Table II. Frequency and percentages for levels of willingness to participate in the PES

Level of Willingness	N	Percentage
1 Not at all willing	189	37.4
2	70	13.9
3 Neutral	95	18.8
4	90	17.8
5 Very willing	61	12.1

Demographic factors and willingness to participate in reproductive health trial

Tables III to VIII present willingness to take part in the PES in relation to age, education, continent of origin, relationship status, number of children and ethnicity. Higher numbers indicate a greater reported willingness to take part in the PES.

Table III. Cross table of participants' age and willingness to take part in the PES.

Willingness	18-27	28-37	38-47	48-57	58+
1 Not willing	30% (87)	49% (38)	44% (34)	48% (20)	57% (8)
2	17% (49)	13% (10)	5% (4)	12% (5)	7% (1)
3 Neutral	22% (63)	13% (10)	19% (15)	14% (6)	7% (1)
4	19% (55)	12% (9)	21% (16)	17% (7)	21% (3)
5 Very willing	12% (36)	13% (10)	12% (9)	10% (4)	7% (1)
Total No.	290	77	78	42	18
Sample %	57.4%	15.2%	15.5%	8.3%	3.7%

Ordinal regression was used to test the relationship between age groups and ratings of willingness to participate in the PES. The results showed that lower ratings of willingness to take part in the PES were more likely as participants' age increased. Age was found to be significantly[9] related to ratings of willingness to take part in the PES (Chi Square 9.7, df=4, p=0.045).

Table IV. Cross table of participants' education and willingness to take part in the PES.

Willingness	SAT	GCSE	NVQ	Apprentice	A Level	Graduate	Post Graduate
1 Not willing	36% (10)	29% (12)	36% (9)	40% (38)	36% (36)	37% (57)	45% (27)
2	11% (3)	27% (11)	16% (4)	11% (10)	10% (10)	15% (24)	13% (8)
3 Neutral	18% (5)	27% (11)	8% (2)	20% (19)	21% (21)	18% (28)	15% (9)
4	14% (4)	12% (5)	28% (7)	17% (16)	26% (26)	17% (27)	8% (5)
5 V. willing	21% (6)	5% (2)	12% (3)	12% (11)	8% (8)	13% (20)	18% (11)
N	28	41	25	94	101	156	60
Sample %	5.5%	8.1%	5%	18.6%	20%	30.9%	11.9%

No relationship was found between a participants' level of educational attainment and their reported level of willingness to take part in the PES. Model fitting information

[9] A 5% significance level was used for all analyses unless otherwise stated

reported that education did not predict levels of willingness (Chi Square=1.94, df=6, p=0.925).

Table V. Cross table of participants' continent of origin and willingness to take part in the PES.

Willingness	Europe	Asia & Africa	America	Australasia
1 Not willing	41% (102)	30% (8)	36% (66)	27% (13)
2	15% (38)	22% (6)	13% (23)	6% (3)
3 Neutral	18% (46)	22% (6)	18% (32)	23% (11)
4	17% (42)	15% (4)	17% (31)	27% (13)
5 Very willing	8% (21)	11% (3)	16% (29)	17% (8)
N=	249	27	181	48
Sample %	49.3%	5.4%	35.8%	9.5%

Participants continent of origin significantly predicted their reported willingness to take part in the PES (Chi Square=8.3, df=3, p=0.034) with participants from Australasia being the most willing to take part in the PES.

Table VI. Cross table of participants' ethnicity and willingness to take part in a PES.

Willingness	White	Mixed	Asian	Black	Other
1 Not willing	38% (166)	30% (6)	40% (10)	33% (2)	28% (5)
2	14% (59)	25% (5)	16% (4)	0% (0)	11% (2)
3 Neutral	18% (80)	20% (4)	12% (3)	50% (3)	28% (5)
4	19% (81)	10% (2)	20% (5)	0% (0)	11% (2)
5 V. willing	11% (50)	15% (3)	12% (3)	17% (1)	22% (4)
N=	436	20	25	6	18
Sample %	86.3%	4%	5%	1.2%	3.6%

No significant relationships were found between a participants' ethnicity and their reported willingness to take part in the PES.

Table VII. Cross table of participants' relationship status and willingness to take part in the PES.

Willingness	Single	LT relationship	Married, divorced or widowed
1 Not at all willing	29% (67)	37% (53)	54% (69)
2	14% (32)	17% (24)	11% (14)
3 Neutral	22% (52)	22% (31)	9% (12)
4	20% (47)	16% (23)	16% (20)
5 Very willing	16% (37)	8% (12)	9% (12)
N=	235	143	127
Sample %	46.5%	28.3%	25.2%

Participants' relationship status was found to significantly predict their reported willingness to take part in the PES (Chi Square=20.8, df=2, $p<0.001$). Participants who were single were significantly more likely to report greater willingness to take part in the PES than people in long term relationships (beta estimate=0.921,df=1, p=0.000).

Table VIII. Cross table of participants' number of children and willingness to take part in a PES.

Willingness	0	1	2	3+
1 Not willing	32% (155)	35% (13)	48% (28)	61% (33)
2	15% (53)	16% (6)	12% (7)	7% (4)
3 Neutral	22% (80)	8% (3)	14% (8)	7% (4)
4	18% (64)	22% (8)	21% (12)	11% (6)
5 Very willing	12% (44)	19% (7)	5% (3)	13% (7)
N=	356	37	58	54
Sample %	70.5%	7.3%	11.5%	10.7%

The number of children a participant had significantly predicted their reported willingness to take part in the PES (Chi square=13.6, df=3, p=0.004). Participants with two or more children reported lower levels of willingness to take part in the PES, than people with one or no children.

Masculinity and willingness to participate in the PES

Higher scores on the MQ were significantly related to greater reported willingness to participate in the PES (beta estimate=0.010, df=1, p=0.022). As individual variables using ordinal regression, MQ subscales physiological energy (beta estimate=0.046, df=1, p=0.01) and socio-cultural roles (beta estimate=0.027, df=1, p=0.008) significantly predicted participants' level of reported willingness to take part in the PES. When both subscales were used in the ordinal regression model, socio-cultural roles remained a significant predictor of PES participation willingness (b=0.23,df=1,p=0.028), but physiological energy did not (b=0.034,df=1,p=0.063).

The following subscales of the MQ were *not* statistically significant as predictors for participants' willingness to take part in the PES; physical characteristics (beta estimate =-0.002,df=1,p=0.942); idealised gender (b=0.012, df=1, p=0.498); sexual preference (b=0.012, df=1, p=0.498);subjective gender identity (b= 0.008, df=1, p=0.640); gender related age identity (b=0.017, df=1, p=0.436); gender related national identity (b=-0.023, df=1, p=0.173); lust (b=0.022,df=1,p=0.330); and male eroticism (b=0.018, df=1,p=0.362).

Altruism and willingness to participate in PES

Higher scores on the altruism scale were significantly associated with a greater degree of willingness to participate in the PES (beta estimate=0.24, df=1, p=0.002).

Background analysis; demographics, masculinity and altruism

Analysis of plotted distributions checked that predictor variables going into the ordinal regression were not too strongly associated with each other. Spearman's rho was used to calculate the significance of correlations. Age was significantly correlated with

relationship status (r(505)=0.569, p<0.001) and number of children (r(505)=0.643, p<0.001). Number of children was also significantly correlated with relationship status (r(505)=0.580, p<0.001).

Demographics, masculinity, altruism and willingness to participate in the reproductive health trial

Demographic factors (age, continent, relationship status and number of children) and co-variables (altruism, masculine physiological energy and gender related socio-cultural roles), found to be significant predictors of willingness ratings, were analysed together using ordinal regression (Appendix 15). Table IX shows the beta estimates and p values for factors and variables.

Table IX. Factor and co-variable ordinal regression output for dependent variable willingness to take part in PES.

	Estimate	Std. Error	Wald	df	Sig.
Physiological Energy	0.022	0.02	1.166	1	0.28
Socio cultural roles	0.026	0.011	5.049	1	0.025*
Altruism scale	0.03	0.009	10.836	1	0.001**
[Children=0]	0.317	0.317	1	1	0.317
[Children=1]	0.928	0.398	5.448	1	0.02*
[Children=2+]	0[a]	.	.	0	.
[Relationship= single]	0.675	0.306	4.861	1	0.027*
[Relationship= long term]	0.29	0.302	0.918	1	0.338
[Relationship= married]	0[a]	.	.	0	.
[Continent=Asia & Africa]	0.014	0.386	0.001	1	0.97
[Continent=Americas]	0.166	0.201	0.681	1	0.409
[Continent=Australasia]	0.676	0.296	5.219	1	0.022*
[Continent=Europe]	0[a]	.	.	0	.
[Age=18-27]	0.601	0.275	4.758	1	0.029*
[Age=28-37]	0.268	0.386	0.482	1	0.487
[Age=38-47]	0.493	0.337	2.139	1	0.144
[Age=47+]	0[a]	.	.	0	.

*p<0.05 **p<0.01

MQ subscale socio-cultural roles and altruism remained significant positive predictors of reported willingness to take part in the PES. Demographic factors such as having one child, being single, being from Australasia, and being in the age group 18-27 also remained significantly positively related to willingness to take part in the PES.

Masculinity and Altruism

Spearman's rho was used to analyse correlations between dimensions of masculinity and altruism (Appendix 16). Dimensions on the MQ of physical characteristics ($r(461)=0.102$, $p=0.029$), idealised gender ($r(456)=0.131$, $p=0.005$), subjective gender identity ($r(451)=0.232$, $p<0.001$) and lust ($r(459)=-0.238$, $p<0.001$) were significantly correlated to scores on the AQ at the 0.05 level. However, correlations between the dimensions of masculinity and altruism were all weak ($r<0.25$) and statistical significance may have been due to the sample size. The remaining dimensions of the MQ were not significantly correlated with scores on the AQ at the 0.05 level.

Content Analysis Results

Participants' reasons for taking part in the PES are shown in table X. Helping and altruism were the most frequent reasons given by male participants to take part in the PES (n=145). Practical reasons (financial incentive, PES deemed not too burdensome) were the second most frequently stated reasons (n=84).

Table X. Qualitative comments about reasons FOR taking part in the PES.

Reason	Frequency (n=)
Helping	**145**
Altruism; helping science / helping fellow man	92
Answering scientific questions (i.e. condom use, pregnancy, evidence)	36
Good intentions of the study / worthwhile / legitimate study	17
Practical	**84**
Money	73
Not too burdensome (i.e. travel, embarrassment)	10
Anonymity	1
Interest	**53**
Interest/ curiosity	31
Funny / fun / enjoyable	12
Experience / adventure	6
Social discussion	3
Relieve boredom	1
Health	**58**
Knowing sperm count	57
Related health problems	1

Participants' reasons for not taking part in the PES are listed in table XI. Practical reasons (n=168) were the most frequent reasons given by participants for not taking part in the PES. Embarrassment (n=74) and privacy concerns (n=40) were the second and third most frequent reasons given.

Table XI. Qualitative comments about reasons for NOT taking part in the PES.

Reason	Frequency (N=)
Practical	**168**
Time constraints	64
Inadequate financial incentive	34
Travel distance	49
Not enough study information	10
Non drop in	4
Partner refusal	7
Embarrassment	**74**
Embarrassment / Awkwardness	57
Location (women & children department)	17
Interest in PES	**34**
Worthwhile research question	12
No interest in study	22
Health concerns	**34**
Sperm count results refusal	7
Vasectomy	23
Age	4
Privacy concerns	**40**
Legitimacy of research	13
Sample use concern	17
Privacy concerns	10

Table XII lists participants' opinions of how masculine they perceived taking part in the PES would be. Over a third of responders to the question (n=43) believed that taking part in the PES had no bearing on their concept of masculinity. Over half of responders thought that the study *was* related to masculinity although responses varied from seeing participation as not at all masculine (n=27) to fairly / very masculine (n=32). Eight responders thought that taking part in the study was gender neutral and those who elaborated on their responses stated that different aspects of the study were perceived as either highly masculine or non masculine. For example, many responders suggested that 'helping others' was seen as a non-masculine motivation, whereas overcoming

embarrassment and being assertive in taking part was described as a masculine behaviour.

Table XII. Qualitative comments about how masculine or manly taking part the PES is perceived to be.

Masculinity rating	Frequency (n=)
Not at all masculine (opposite of masculine)	27
Fairly / very masculine	34
Neutral*	8
PES participation not related to masculinity	43
No interest / Don't know / Individual perception	13

*Participants perceived aspects of the study as both highly masculine behaviours and not at all masculine behaviours (opposite of masculine).

Discussion – Study 1

The primary aim of study 1 was to examine what factors (demographics, altruism and masculinity) may predict a participant's willingness to take part in a reproductive health trial (RHT). Secondly, the study aimed to explore whether men think masculinity or other individual factors may influence their willingness to take part in a RHT.

Results replicated previous research indicating that men are generally unwilling to take part in RHTs (Muller, et al., 2004). Willingness ratings were also consistent with those of non-clinical respondents who are asked to enter clinical trials (Sanderson, in preparation). Analysis of the results suggested that men who were younger, single, had fewer children and were from Australasia, were more likely to take part in the PES than men from other demographic groups. Education and ethnicity did not influence men's

willingness to participate in the PES in this study. Altruism was found to be a strong predictor of willingness to take part in the PES. When analysed as a co-variant with demographic factors and altruism, only the 'socio-cultural roles' dimension of the MQ remained a significant predictor of willingness to take part in the RHT. Dimensions of masculinity and altruism were shown to have low but significant correlations.

Overall, the results were consistent with suggestions that potential participants employ a 'personal account balance' when deciding to enter a RHT (Verheggen, Nieman, & Jonkers, 1998). Participants weigh up drivers and barriers to participation before deciding to enter a trial. The personal significance of these factors is influenced by participant's background (Verheggen, Nieman, & Jonkers, 1998).

Demographic factors

Results showed that younger, single men with fewer children were more willing to take part in the PES. The findings replicated previous research which suggested that younger men are more willing (than older men) to take part in RHTs (Muller, et al., 2004) and clinical trials (Trauth, et al, 2000). The nature of the PES may have influenced differences between demographic groups. The PES advertisement (Appendix 13) discussed fertility and condom use. Younger, single men with fewer children are more likely to be concerned about fertility and family planning (than older, married men who already have a family) as intimacy and generativity are key stages in their present to near future psychosexual identity development (Erikson, 1968). Survey responders also suggested that interest or 'no interest' in the PES were drivers (n=31) and barriers (n=22) to participation. Knowing one's sperm count (n=57) and answering questions about pregnancy and condom use (n=36) were quoted as reasons for participating in the PES. Men described how they would often be unwilling to take part in the RHT if they

already had children, if they were older, or had had a vasectomy. Sperm count results seem more important to younger men without children. This may be due to greater uncertainty about their fertility. In contrast, participants who are older, married or have had children, may be satisfied with their fertility or perceive RH as less of a priority.

In contrast to previous research, ethnicity and educational attainment (Muller, et al., 2004; Trauth, et al, 2000) did not seem to influence men's willingness to take part in the PES. The recruitment of English speaking participants and problems generalising educational attainment across continents may have influenced these findings (see limitations).

Interestingly, men from Australasia were much more willing to enter the PES than those from other continents. To date, there has been little research into regional differences of attitudes towards participation in clinical trials, let alone RHTs. The low number of participants (n=48) from Australasia in this study is also a limitation. Further research into regional differences of willingness to take part in clinical research trials is needed. Without further research, only speculation about possible factors underlying differences found in this study can be achieved. It may be that clinical trials in general are seen as more appealing in Australasian culture, or that people from Australasia have general trends in certain traits (i.e. altruism or lower levels of awkwardness) which influence their willingness to participate. Research Australia (2008) suggests that 68% of Australians would be willing to participate in clinical trials, a much higher percentage than the median willingness to participate in clinical trials (25-46%) found in a systematic literature review of non-clinical participants (Sanderson, in preparation).

Masculinity

Results of this study suggested that overall masculinity did not influence RHT participation. Most dimensions of the MQ did not correlate with reported willingness to take part in the PES. Interestingly, 43 men also commented that participation in the PES did not relate to the concept of masculinity in any way. However, other men also perceived participating in the PES as a very masculine behaviour (n=34), or in contrast an emasculate behaviour (n=22). Men commented that the altruistic side of participation was emasculate, although the aspect of overcoming anxiety and embarrassment to take part was deemed a highly masculine behaviour. Comments are consistent with research into social constructions of masculinity; with courageousness and assertiveness constructed as a masculine behaviour (Golombok & Fivush, 1994). Taking part in health promoting behaviours is often seen as emasculate (Inhorn, 2004). Gender stereotypes often become widely shared beliefs about how men should act (Pleck, 1987). It seems that the idea of participating in the PES may have caused a feeling of uncertainty or conflict in men's self-construction of masculinity. Avoidance of this conflict could be one reason why the majority of males are unwilling to participate in RHTs.

Questionnaire results also showed that men who saw traits such as assertiveness and dominance as desirable were more willing to take part in the PES. The dimension of Physiological Energy measured levels of testosterone by asking how desirable it is to be aggressive, assertive, competitive and dominant in society. A significant positive relationship between Physiological Energy and willingness to take part in the PES suggested that men who see traits associated with high levels of testosterone as desirable were more likely to take part in the PES. Greater willingness to participate in the PES may be because the value given to assertive and dominant behaviours

outweighed the negative value attached to helping or health promoting behaviours. However, this finding lost significance when demographic factors and co-variables were included in the analysis.

Scores on the socio-cultural roles (SCR) dimension of the MQ remained a significant predictor of willingness ratings when analysed with demographic factors and co-variables. SCR measured the roles (i.e. follow sports teams' results, wear team colours) which men are expected to perform in order to be perceived as masculine within Western culture. Wearing a sports team's colours and passionately following their team's results may also suggest a willingness to be seen as part of a masculine group. SCR could have been a significant predictor of PES participation because similar to following a sports team, participating in the PES may have been constructed as a role that men should play to be part of a masculine group.

The relationship between masculinity and willingness to take part in the PES contradicted the original hypothesis, that stated PES participation would be perceived as a 'health promoting behaviour' and a threat to masculinity (Courtenay, McCreary, & Merighi, 2002). Therefore, it was assumed that participants who perceived themselves as more masculine would be less willing to take part in the PES. Health promoting behaviours may be less of a threat to masculinity to younger men due to different cohort beliefs. Going to the doctors may no longer be viewed as such an emasculate behaviour for younger generations of men. This may explain why younger men were more willing than older men to take part in the PES. However, it may also have been that the PES was not perceived as a 'health promoting behaviour' or that there were other more salient aspects of the PES in relation to masculinity.

Altruism

Altruism was found to be the most significant predictor of participation in the PES. This meant that men who have in the past helped strangers (i.e. push a car, give change) and organisations (i.e. donate blood, help charity) were much more likely to take part in the PES. Altruism was also quoted most frequently (n=92) as a reason for taking part in a clinical trial. Content analysis of participant's comments found that 'helping science' and 'helping a fellow man' were the most frequent reasons given by participants in relation to helping. Altruism has previously been found to influence a participant's willingness to take part in clinical trials (Trauth, et al, 2000; Kennedy & Burnett, 2007) and semen donation (Handelsman, Dunn, Conway, Boylan, & Jansen, 1985); hence, results are consistent with previous literature. The presence of truly altruistic behaviour has been questioned and it is possible that participants described altruistic reasons in an attempt to provide a 'moral account' of their actions (Healy, 2006). Participants' concerns about how 'important' the PES was are consistent with Lawler and Thye's (1999) social exchange theory, whereby people try to maximise the ratio of social rewards to social costs. Similar to the 'personal account balance' theory, if social rewards of the study (i.e. important research which leads to better lives for many) increase and costs decrease (i.e. less burden) then people are more likely to participate.

Limitations

Sample bias may have occurred as only men who chose to respond to the internet advertisement took part, excluding men without access to the internet. However, Gosling, Vazire, Srivastava & John (2004) report that internet samples are 'relatively diverse demographically' and 'internet findings generalise across presentation formats, are not adversely affected by non-serious or repeat responders, and are consistent with findings from traditional methods'.

The advert aimed to be provocative to ensure recruitment of an adequate sample size. This included using a female model to advertise the survey online. However, this may have biased the sample of men who chose to take part, as men with a preference for females may be over-represented. Results from the MQ suggested that there were no significant differences in rating of willingness to take part in the PES, between men with a sexual preference for males or females.

The study only measured willingness to participate and it is uncertain if this necessarily equates to behavioural participation. The study was unable to account for the difference between a stated intention (willingness) and behaviour (participation). Theory of reasoned action (TRA) (Ajzen and Fishbein, 1980) states that if a person intends to do something, then it is likely that they will do it. TRA suggests behavioural intention (BI) depends on a person's attitude about the behaviour (A) and the influence of subjective norms (SN) (BI = A + SN). Subjective norms are the influence of one's social environment on behaviour intentions. The study was unable to account for factors that occur between stating an intention and participation. For example, a participant may report high willingness to participate (attitude) on the survey and then discuss participation with their partner or friend, who describes negative views about participation (subjective norm). If the participant is influenced by the views of others, then they may then decide not to participate.

The study recruited English-speaking people over the internet and included 256 men from outside of Europe. Survey choices for educational attainment may not have generalised to other countries. Recruitment from English speaking websites may have reduced ethnic diversity of participants as the majority of participants were white

(n=436). Therefore, the findings of the study are only applicable to white western culture.

There were also inherent problems with the construction and measurement of masculinity and altruism. The MQ and AQ enabled a large sample of men to quantify concepts of masculinity and altruism. Quantifying masculinity and altruism allowed hypotheses about their impact on willingness to take part in RHTs to be tested. However, masculinity and altruism are socially constructed (Moynihan, 1998) and therefore likely to differ between individuals and cultures. Although not the aim, the study was unable to measure if RHTs posed a threat to an individual's masculinity. It may be that perceived threat to masculinity, as opposed to self-perceptions of masculinity, influence willingness to participate in RHTs.

Further research

Further research should aim to provide a more in depth and detailed understanding of how individual men construct, and attach meaning to, masculinity and altruism in relation to RHTs. This could include an exploration of a possible threat to masculinity posed by trial participation. Although participants' comments suggested that altruism, and to some degree masculinity, were drivers and barriers to PES participation, they did not explain these factors in detail. To date, there have been no published articles qualitatively exploring the reasons that influence participation in a male reproductive health trial. A qualitative methodology would allow for a much more in depth and detailed understanding of how individual men construct, and attach meaning to, masculinity and altruism in relation to RHTs.

Aim of study 2

To qualitatively explore men's reasons for participating in a RHT; to investigate the complex interactions between masculinity, altruism and RHT participation; to consider the individual experience of taking part in a RHT.

Research questions

1. What are the drivers and barriers to participation in a male RHT?
2. What is the experience of men participating in a RHT?
3. How does masculinity influence participation in a RHT?
4. How does altruism influence participation in a RHT?

Method

Recruitment

Participants were recruited from the online study conducted in study one. A detailed account of participant recruitment is described in the method of study one (pg 59). Of the 521 participants who filled out the online survey, 52 men left details to be contacted for an interview about their experience of taking part in a pre-ejaculatory fluid study (PES), conducted at a local IVF unit (Killick, Leary, Trussell, & Guthrie, In submission). Participants who left contact details suggesting that they resided out of the local area were excluded. Men were then selected in order of participation. Ten men were initially contacted; six confirmed that they had completed the PES; and five men agreed to be interviewed.

Participants

The five interviewees were aged between 22 and 25, with a mean age of 23. Four of the participants were university graduates and one was educated up to the age of 17. Three

of the men were in long-term relationships and two were single. None of the men reported having any children or health problems.

Measures (Appendix 17)

Questions on the interview schedule aimed to examine participants' subjective drivers, barriers and experience of PES participation. Items on the schedule then assessed the influence of masculinity and altruism on PES participation, using dimensions of the Perceived Masculinity Scale (MQ: Chesebro & Fuse, 2001) as a framework. The interview schedule was reviewed and adjustments were made, following expert opinion from a Professor in the field of Obstetrics and Gynaecology at a local University, and members of the research staff team at the local In-Vitro Fertilisation (IVF) unit.

Analysis procedure

Interviews were transcribed then checked for accuracy against original recordings. Three out of five participants also checked their transcripts were a true representation, before they were anonymised. Once all interviews were completed, each interview was analysed individually. Analysis followed guidelines described by Smith, Flowers & Larkin (2009), presented in Figure II. Transcripts were read several times and notes were made in the left hand margin, next to extracts of interest. This procedure was also undertaken by a research supervisor (female, 3 transcripts), a local Professor in the field of Obstetrics and Gynaecology (male, 2 transcripts) and a Trainee Clinical Psychologist (female, 5 transcripts). The initial notes from each individual transcript were reviewed and emerging themes were recorded (Appendix 18). Male and female colleagues analysed transcripts in order to account for gender-influenced interpretations. Emerging themes were discussed between the researcher and co-analysts. This process was consistent with recommendations to make use of 'supervision, collaboration, or audit to

help test and develop the coherence and plausibility of interpretation' (Smith, Flowers & Larkin, pg 80, 2009). A discussion of interpretations allowed for a deeper exploration of themes and endeavoured to use inter-rater comparisons to check validity of interpretations. Connections were then made between themes and transcripts. Two interviewees were consulted about developed themes for member validation. Super-ordinate themes were compared across transcripts and included in the analysis if they occurred in over half the sample (table XIII).

Figure II. Analysis procedure

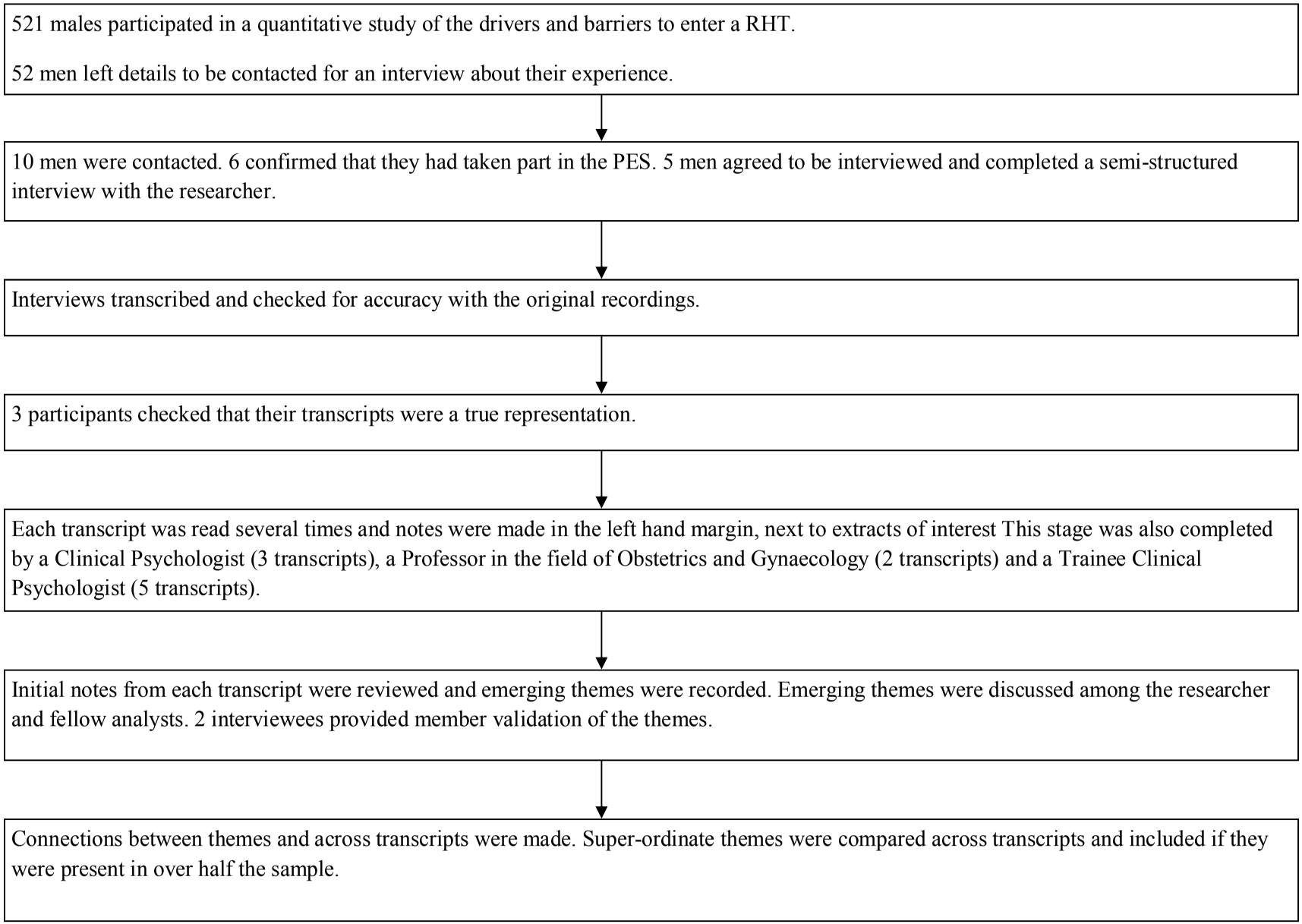


Table XIII. Recurrence of super-ordinate themes across participants

Participant	Conflict in decision making; doing a 'good thing' versus the shame associated with a 'socially frowned upon' act	Performance anxiety; 'less of a man'	Humour: coping strategies, stigma or the desire to be seen as cool in the face of adversity
1	YES	YES	YES
2	YES	YES	YES
3	YES	YES	YES
4	YES	YES	YES
5	YES	YES	YES

Results

Three super-ordinate themes were evident in all of the participants' transcripts (Table XIII).

1.) A conflict in decision making; doing a 'good thing' versus the shame associated with a 'socially frowned upon' act

Altruism

Participants seemed to have conflicting views about the morality of taking part in the pre-ejaculatory fluid study (PES). Altruistic conceptualisations; such as doing something 'good' or helpful, were frequently given as reasons for taking part in the PES.

"The majority of people thought it was a good thing to be doing because obviously it's for a good cause." (P2).

"I feel proud of it because I think participating in anything where there is some positive gain in terms of health research, that's fantastic." (P3).

"Just helping. I quite like, cos I don't do much....I'd be more inclined and definitely think about it a lot more if I knew that I could be helping something." (P1)

Participants 1-3 described a moral element to their behaviour, suggesting they were 'proud' to participate in research. Research in this study was experienced as a 'good cause' that could 'help something'. However, all participants initially stated that they took part in the PES for 'the money' (expenses of £10 were given to participants by the department conducting the PES). Only later in the interview schedule did interviewees begin to describe the importance of altruism as a motivational factor for participating. Participants 1, 3 and 5 suggested that 'helping behaviours' are not seen as particularly masculine. Therefore, helping may not have been given as a reason to take part in the PES until the interviewee felt more relaxed with the researcher.

"If in like my head I had an ideal masculine man I can't imagine he went and did sexual reproductive studies. I don't think it's, no I just, the two don't really go together in my head…thinking about an ideal masculine man, I always seem to think of like a lad's lad, someone who doesn't do, I wouldn't say the opposite of that but someone who doesn't really think about things like that and doesn't, it's not on their list of things to do." (P1).

"Influenced – I think if I wanted to be really, really masculine I probably wouldn't have gone through with the study, don't know for some reason it's more masculine not to expect help." (P5).

"If you wanted to appeal to the sort of the less masculine side then you'd have to really promote the positive altruistic aspects of it" (P3).

Interviewees may have given money as their primary reason as it fits with the masculine stereotype of a 'breadwinner' or 'provider'. Words such as 'task', 'job' and 'earned' (P1-2) were used by interviewees to describe their experience of the PES. It may be that 'earning' £10 (even though the £10 was advertised as 'expenses') was perceived as a socially acceptable reason, as a male, to give for taking part in the PES. In contrast, helping or being helped was not construed as a masculine behaviour, in relation to reproductive health. Intriguingly, the belief that helping by participating in RHTs is not a particularly masculine behaviour seemed to be in conflict with the threat to masculinity, associated with being seen as afraid or unwilling to take part.

It's not urgent… not like giving blood

Interviewees suggested altruism was a driver for participation; although helping behaviours may not be seen as masculine and may not appeal to a 'lad's lad' (highly masculine male). Despite altruism being given as a reason for taking part in the PES, it seemed that participation was not viewed as particularly important or urgent. For example, participant 1 described the difference in perceived importance between donating blood and giving semen for research:

"I think it's not on the same level as giving blood for example but I do think that if something was found out to be important and it was an important discovery then yeah it could be but like I say people put more emphasis on other people who say give blood…obviously it's needed for operations and things so there's a lot more sort of urgency about give blood, keep people alive but you don't have that sort of, give semen, find out whether pre-cum contains sperm, like there's not, it's sort of an urgency or something like that." (P1).

Perceptions that PES participation is not important are likely to reduce men's willingness to enter the study. Reproductive health problems seemed not to be thought about, or talked about, in this sample of men. Interviewees also seemed to have very little empathy for people with reproductive health problems and research into RH did not seem to be thought about. It may be that men do not talk about RH problems, due to stigma associated with masturbation, or having a reproductive health problem.

Interestingly, when interviewee's perceived that participation was more urgent or important, they were more willing to take part in the PES. For example, participants 1 and 3 described how they were more willing to take part in the PES as they were 'close to the subject' or it was 'suggested by somebody they knew'. When participants viewed their involvement in the study as not only helpful but needed, for example if there was a 'shortage of white males', they seemed much more willing to take part:

"The fact that it was suggested by someone I knew then that probably influenced me more so I would think but it being a good deed was definitely a part." (P1).

"If there was a shortage of white males taking part then I think then it would have affected (decision to take part)" (P1).

> "I think I wouldn't have taken part in this one had I not have been, I don't know so close to the sort of subject if that makes any sense but I, due to the fact that it wasn't well explained, I wouldn't just jump in and do another one." (P3).

'Socially frowned upon'

The moral justification for taking part in the PES appeared to be in conflict with the stigma attributed to the act of masturbation, required for the PES.

> "People who I've spoken to about it, some people have been almost prudish about it which I don't understand because it's not like you were just doing it in public, it was for an experiment in a medical facility so it wasn't anything disgusting about it….they just found it all a bit bizarre" (P2)
>
> "I think obviously the embarrassment factor and what they think other people will think of them for doing it and what they think the process is like" (P5)
>
> "I certainly perceived people looking at me and wondering why I was there but I suppose really getting down to it, it's the potentially slightly socially on the face of it, socially frowned upon masturbation activity that was required and yeah there's still some social or cultural taboo about that." (P3)
>
> "I think I could have definitely done something else I would have rather done than that to satisfy myself but yeah that was due to all of the build up the anxiety and the nervousness." (P1)

Other people's perceptions of the PES were described as 'bizarre', 'disgusting', 'socially frowned upon' and 'taboo'. It is likely that other people's beliefs influenced or even reflected participants own thinking about the PES. Positive aspects of helping science seemed to conflict with stigma associated with masturbation. Participant 2

seemed to dispute negative perceptions about the PES, giving a moral explanation how it was for an 'experiment in a medical facility'. His account seemed to be an attempt to persuade himself, as well as the interviewer, of the moral reasons for participation. The extract portrays the ambivalence of feelings towards the PES, from feeling proud of participating in medical research to feeling ashamed in relation to stigma associated with masturbation. It seems that similar to financial rewards and helping behaviours, stigma associated with the PES influenced the decision making process. Once the individual had taken part in the PES, participants began a process of rationalising their behaviour, to give a moral account of their actions. This can also been seen in the extract from participant 1, suggesting that he 'could have definitely done something else he would have rather done'. Due to the shame associated with masturbation in hospital, it seems that accounts were given to distance themselves from the perceived 'deviant' position of enjoying PES participation. Instead, the study was conceptualised as a 'task' that 'needed to be done' (P2).

Masturbation is not talked about and semen is a 'waste product'

Participant 3 described how masturbation is not discussed in his culture and semen was conceptualised as a 'waste product', which would normally be cleared up and hidden:

> "You don't go and talk about your masturbation success with your male mates at the park and you wouldn't do it with females either. It's still an individual thing so all this gender is irrelevant to some extent…
> The fact that that's the taboo thing to do and you've done it in a hospital and then you're presenting the contents of that which again as a waste product, there's a taboo about that as well so there might be something about that there as well that

you know, here's something you'd usually clean up you know, to have any evidence of and you're presenting it all to someone." (P3).

It is interesting that semen is described almost shamefully as a 'waste product'. This is in contradiction to the view of medical researchers, who value donations of semen and describe how research into ejaculatory fluid is often under resourced. The shame associated with masturbation seems to be an important factor in the avoidance of talking about, and taking part in, reproductive health research.

2.) Performance anxiety; feeling 'less of a man'

The importance of masculinity

Initially, interviewees' did not consciously link participation in the PES with their concept of masculinity. As interviews progressed, the relationship between masculinity and the PES became more apparent. It may be that participants in the study did not have a clear concept of what masculinity meant to them. Although descriptions of the meaning of masculinity seemed difficult to verbalise, interviewees' acknowledged that it was important for them to be seen as masculine.

"I think probably I wouldn't like to say but obviously consciously I would have said being male and probably like most males like yeah it's important, sorts the social pecking orders that are just like formed naturally but like obviously it's important to everyone, nobody wants to be at the bottom of that pecking order do they?" (P4)

"I'd say it's quite important. I like to be seen as masculine particularly with a female. You want to be seen as masculine. You don't want to, I don't want to be

like an alpha male sort of thing that you get with some people but I like to be quite masculine." (P5)

Masculinity appeared to be important for participants in relationships with both genders, although interviewees preferred to be seen somewhere in the middle of a continuum of masculinity. Being 'masculine' seemed important in relation to social dominance ('pecking order') with other men. Participant 5 described the importance of being seen as masculine with females, suggesting the perceived desirability of masculine traits in sexual situations.

Catastrophic predictions

As described earlier, interviewed men described the PES as a 'job', 'task' or something that 'needed to be done'. They also described a level of anxiety, or 'stage fight' (P2), about taking part in the PES:

"But it was just the whole, the build up to it, the banter, the going through in your head what you're thinking, you get yourself a bit het up sometimes if you don't know what to expect. Like I say, once I was there I was fine." (P2).

"About the unknown… how the sample was going to be taken. Obviously you think of sort of sexual tests for things like STDs that doesn't make you think happy thoughts so if it was anything like that I would have been put off and probably wouldn't have actually done the tests, if it was anything to do with a swab I was going to leave. …. If I'd have known then it would have been a lot less nerve racking I think." (P1).

Interviewees suggested they were initially anxious about what the PES entailed and described a fear of the 'unknown'. Uncertainty about trial procedures seemed to cause catastrophic predictions. Participant 1 appeared to base his predictions on previous negative experiences of sexual health clinics; including fearful thoughts about medical testing and the use of 'swabs'. It is interesting how interviewees associated the PES with the stigmatised area of sexually transmitted disease (STDs). Catastrophic predictions, resulting from an uncertainty about the PES procedures, are likely to be a barrier to participation.

Exposure: modification of catastrophic thoughts

Once participants had taken part in the PES, they reported a much greater willingness to take part in future RHTs. The experience of participation seemed to modify beliefs about RHTs and resulted in participants' feeling more relaxed about the procedure.

> "It was a lot easier than I thought – a lot more relaxed than I was expecting. I wouldn't call it a pleasurable experience but I would probably do it again." (P1).
>
> "You never know what it's going to be like until you've tried something. Now I've done it I'd quite happily do a study like that again." (P2).
>
> "I'm more willing to do it now that I've actually done it. I just don't know what I was getting embarrassed about to be honest. It was fine." (P3).

Participants 1-3 described feelings 'fine', 'relaxed' and 'happy to do it again'. It may be that interviewees have tried to minimise their feelings of anxiety, as being viewed as fearful or anxious may not be seen as socially acceptable for a male in this situation.

The 'lad mentality' versus the 'inadequacy' in failure

Desires to be seen as 'one of the lads' by being courageous and taking part in the PES, seemed to conflict with a fear of 'failing to perform'.

> "Probably just the way I perceive myself like I suppose it's part of the 'lad' mentality isn't it, one of the lads and you don't want to be one of the people that doesn't do something or can't do something." (P2).
>
> "There's a lot of pressure at the time you feel because you're in this very strange environment and you're, it's, you're doing this as a means to an end for a study…you don't want that setting or that peculiarity being able to beat you being able to do it because the activity usually requires you to be relaxed and comfortable so in that respect I suppose it's a challenge to your ability to do that and maybe that's a challenge to your masculinity. It is an assessment of whether you can produce this, conduct this activity." (P3).
>
> "Failure to perform, something like that. That would have been embarrassing……Just the fact that I knew the people that I was going with. There was more than one of us there…actually embarrassing even with someone you've never met like the woman. If I came out it was like…
>
> Researcher: About not being able to perform... What would that mean?
>
> Inadequacy… yeah less of a man." (P1)

Interviewees described a social pressure to be able to 'perform' in the situation. Words such as 'assessment', 'challenge' and being 'beaten' conveyed a perception that the PES was testing their masculinity. A failure to 'perform' in the study connected to feelings of 'inadequacy' and a threat to masculinity. Participant 3 explained that anxiety about

being able to produce a semen sample, in a strange setting, was perpetuated by a perceived need to be relaxed in order to 'perform'.

Social comparison and expectations versus the need for peer support

Interviewees' responses encapsulated a powerful theme of social comparison. They described not wanting to 'be the one that can't do it' and conveyed a sense of embarrassment and inadequacy if that were the case.

> "I didn't know how long I should really be in there. I remember two people before me sort of for ages and I was like well, I could finish this experiment in two minutes and I didn't know about being strange or this or that so I purposely hung on for a bit longer." (P5)
>
> "I was thinking if I get stage fright and can't perform then I'll feel a bit stupid telling people. I think I would have felt a little bit, like it was testing my masculinity if I couldn't have done it." (P2)
>
> "If there were three people or if it was a larger group together then it would be sort of, the pressure of just being around your friends, not necessarily the embarrassment but the whole uncomfortableness." (P1)

Participants 1, 2 and 5 described feeling 'embarrassed', 'uncomfortable' and 'stupid' when taking part with their friends. These feelings appeared to relate to a threat to their masculinity, or an uncertainty about being seen as 'normal' in this situation. The desire to be seen as masculine is apparent when participant 5 described how he 'hung on for a bit longer' in order to be seen as the same as the other participants.

However, a strong desire to conduct the PES with other people was also described by interviewees. Being in a group may have helped to manage the feelings of shame, which participants associated with the stigma of participation. Peer support and humour, as discussed later, may also have provided a method of coping with the uncomfortable feelings described by interviewees. However, knowing other men that were participating also seems to have put pressure on interviewees to take part themselves.

> "I wouldn't have gone had I not have been with the people went with. I also don't think I would have gone on my own. I think if it wasn't a social thing, it's, if we hadn't have made it into a social thing, I don't think I would have done it. It was almost that I had to do it with a group. I wouldn't do it on my own." (P1)
>
> "I think if I didn't know other people were doing it, I wouldn't have been the first person to say yes, that's the only thing really…It's the way people perceive me; I didn't want to be seen as not wanting to do it... I was quite interested in how it works but then again my ego wouldn't let me not do it when somebody else was doing it." (P2)

Participant 2 described how his 'ego wouldn't let *him* not do it when somebody else was doing it'. Although helping RHTs was not seen as a masculine behaviour, being seen as unable, or not wanting to participate because of fear or embarrassment, was seen as a much greater threat to masculinity.

Healthy sperm and masculinity

The PES researchers gave participants the choice to find out details about their 'sperm count'.

"It's something like me personally I've never really thought about so yeah it's kind of like everything, it's kind of rushing into your mind at once, a 'what if' question, do you know what I mean? So yeah for about five minutes you do feel I've never actually thought about this is and it's quite, you can measure it by your relief." (P4).

"Erm, potentially just with the desire to know whether my sperm's healthy and everything because I think that's linked with masculinity and I think I obviously wanna know that just in case. That's a by-product of the test obviously being able to find that out. But yeah that's come at an age where if there is something wrong, I can see someone and start doing something about it so yeah, I think in that sense affected me… Probably just going back to the actual like healthiness of the sperm, that's the only reason cos obviously I don't want to be impotent or anything like that" (P1).

Participant 4 suggested that he had not previously thought about the topic. When given the choice to find out his results, he described a 'rush' of anxious thoughts and predictions. The 'healthiness' of sperm was associated with the concept of masculinity for participant 1. It seems that sub fertility was experienced as a serious threat to masculinity for some interviewees and was reflected by participants' experience of relief on finding out they were fertile.

3.) Humour and coping

Difficult feelings associated with participating in the PES, such as shame, embarrassment, anxiety, fear and inadequacy, were described by interviewees. However, all interviewees described their experience of the PES as being much easier than expected. Extracts from interviewees' transcripts indicated how some difficult

feelings were managed. Humour seemed to be a prominent coping strategy used across participants.

> "…a bit nerve racking on the way there, kind of had to keep cracking jokes about it as I was really nervous." (P2)
>
> "Everyone I've spoken to seems to think it's a bit of a joke as in you're doing it for a laugh, not necessarily, there is medical reason behind it obviously but my peers see it as something a bit of fun to do, they don't see it as masculine or anything like that." (P1)
>
> "I think by response with speaking to people after or about it, I think there is quite a bit of like interest like humour brought towards it and I think that's probably due to obviously the situation and what you're actually have to do in the test." (P4)

'Cracking jokes' may have helped to reduce the tension and anxiety associated with participation. However, humour may also have been employed as a method of communicating distance from the stigma they associated with participation in the PES. Making jokes about the PES may also have been a way for participants to demonstrate that they did not take the situation too seriously. It seemed that interviewees did not want to be perceived as having fears or difficulties regarding RH. It may be that men minimised the emotional impact participation in the PES had on them. For example, participant 5 repeated 'no' or 'not' five times, in response to a question asking about feeling fearful in relation to PES participation.

Researcher: Did you have a fear of failure?

"No. No, not, no, not before and during you potentially you realise that you're not as comfortable as you'd normally be so that might be an issue but no I didn't worry about that." (P5).

"Knowing that I would, I don't have difficulties or any sort of feeling uncomfortable affecting whether I can produce what was required for the study meant that because I knew I could rely on myself in that situation, it would be reasonable for me to do it so yeah it's more about just knowing that there wasn't uncertainty in me in my own performance in that situation." (P3).

Humour may help to portray the message to others that 'I'm not really interested in helping', 'I think this is bizarre too' or 'I'm not afraid, I'm having a laugh'. Therefore, humour may be exercised in various ways to cope with difficult feelings associated with stigma and a threat to masculinity.

Analysis of interviewee's transcripts also suggested that men used other strategies to cope with difficult feelings associated with participation. Interviewees described experiencing feelings of anxiety stemming from uncertainty about the study procedure. It may be that interviewees' own anxieties, arising from an underlying threat to their masculinity, were projected onto the PES procedure. Parts of interviewees' responses also appeared to rationalise their behaviour. Although this often provided a detailed account of their experience, it seemed devoid of emotional content. Therefore, interviewees may have intellectualised conversations in an attempt to cope with, or avoid, feeling difficult emotions. There also seemed to be evidence that participants avoided difficult issues.

> "I remembered one of the cups wouldn't shut properly or wouldn't seal properly so I'd sort of kept it a certain way in the bag so it wouldn't get spilled. I had to sort of get that message across to the female who had shown me into the room and I certainly felt a bit awkward doing that because I think at that stage, there's very little eye contact, it's just the case of getting the sample and giving the sample over and getting out and I think they know that as much as you do so they're equally happy to make the transaction as quick as possible." (P3).

Participant 3 describes an attempt to avoid talking about an 'awkward' issue with a female researcher. This extract illustrates the use of avoidance to cope with potentially overwhelming difficult feelings. Low levels of male participation may therefore result from men's use of avoidance, to cope with the difficult feelings associated with participation in RHTs.

Table XIV. Super-ordinate themes and associated sub themes.

Super-ordinate themes and associated sub themes
A conflict in decision making; doing a 'good thing' versus the shame associated with a 'socially frowned upon' act
• *Altruism*
• *It's not urgent… not like giving blood*
• *'Socially frowned upon'*
Performance anxiety; feeling less of a man
• *Importance of masculinity*
• *Catastrophic predictions and exposure*
• *'Lad mentality' versus 'inadequacy' in failure*
• *Social comparisons and peer support*
• *Healthy sperm and masculinity*
Humour and coping
• *Humour*
• *Avoidance, projection, minimisation and intellectualisation*

Discussion – study 2

Overview of findings

An interpretative phenomenological analysis of interviews with men about their experience of RHTs led to the development of three core themes. Stigma associated with masturbation and RH problems were experienced as barriers to RHT participation. Catastrophic predictions about the trial procedure, 'performance anxiety' and an underlying threat to masculinity associated with feelings of 'inadequacy' were also interpreted as barriers to RHT participation. In contrast, a desire to undertake a helping behaviour, to be 'one of the lads' and step up to the challenge, seemed to be drivers to RHT participation. Humour was the most frequently used coping strategy in this sample, although intellectualisation, avoidance and projection were also interpreted as strategies for coping with feelings of shame, anxiety and embarrassment.

Decision making model

Interviewees' decisions to take part in the PES appeared to be based on a cognitive appraisal of the pros and cons of participation. The perceived importance of individual drivers and barriers to participation seemed to vary, depending on how individual participants experienced them. The adapted Health Belief Model (Verheggen, Nieman, & Jonkers, 1998) suggests that potential participants have a 'personal balance account' to assess before consenting to take part in a clinical trial. Similar to accounts from interviewees in this study, Verheggen, et al, (1998) suggests the decision to take part in a trial is calculated by the physical and emotional value that the participant hopes to gain from participation, compared to non participation, minus the expected risks and extra time expected from trial participation. The model also suggests that background factors, beliefs, locus of control, attitudes, expectations and perceptions have an inter-related influence on the decision to participate in a trial.

Stigma of masturbation and reproductive health

Historically, masturbation has been viewed as a 'moral sin' by various religions, including Judaism, Islam and Christianity. Interviewees in this study experienced masturbation as a socially 'taboo act' and reported feeling embarrassed about taking part in the PES. These reports are endorsed by Coleman (2002), who suggests that masturbation tends not to be openly talked about and negative attitudes persist. Feelings of embarrassment and awkwardness have been elicited in previous qualitative research into masturbation (Spencer, Faulkner, & Keegan, 1988). Embarrassment or awkwardness was reported as the second most frequent barrier to PES participation (after practical reasons) by participants in study one.

Interviewees' in study two suggested that perceived stigma associated with entering the PES was less significant when participating in a group. It may be that men used other males as references for appropriate behaviour. Wade (1998) describes 'reference group dependent' males being characterised by psychological relatedness to some males and not others. Feeling socially connected with other males (if social aspects of identity are important for the individual) may help to overcome feelings of shame associated with RHT participation. It may be that when men observe other men (who they feel psychologically related to) enter a RHT, they are reassured that participation is 'normal' and the perceived stigma is reduced or shared.

Altruism

'Doing a good thing' was described by participants as an important reason to take part in the PES trial. Altruism was also the most frequent reason given for PES participation by 505 in an internet survey (study one) and a significant reason to take part in clinical trials for 'healthy' people (Sanderson, in preparation). Suggesting that altruism was the

primary motivation for trial participation might have been a way for the men to rationalise their own behaviour and to communicate a moral character to others. People are much more likely to undertake a voluntary endeavour if they can provide a 'moral account' of their actions (Healy, 2006). Financial incentives described by interviewees at the beginning of interviews may also have reflected an attempt to provide a rationale for their actions. However, interviewees accounts of a sense of pride, or 'feeling good about taking part in the trial, were consistent with findings that people often enjoy the benefit of a 'warm glow' when conducting a helping behaviour (Andreoni, 1990). Altruistic motivations increased when interviewees viewed participation as more urgent or individually relevant. Participants may have been more likely to take part in the PES as low participation rates and the need for men to give their opinion, were communicated in the rationale for the survey. The findings are consistent with the social psychology theory of the bystander effect; where the greater the number of bystanders who witness an event, the less likely any one of them is to help (Latane & Darley, 1970). When men viewed themselves as individually 'needed' or more vital to the success of the study, they may have been more willing to take part.

Similar to findings from study one, there seemed to be some ambivalence regarding altruism and masculinity. Helping behaviours and concerns about reproductive health were constructed as emasculate, as reported elsewhere (Courtenay, 2000). In contrast, being 'one of the lads' and stepping up to take part was constructed as a masculine behaviour. Although some participants in this study reported that being seen as 'masculine' was important to them, none of the participants described themselves as extremely masculine. Therefore, taking part in a helping behaviour such as the PES may not have resulted in the cognitive dissonance possibly experienced by 'extremely masculine' men.

Anxiety and a threat to masculinity

Experiences of PES participation can be mapped onto a traditional cognitive behavioural model of anxiety (Westbrook, Kennerly, & Kirk, 2007). Interviewees described catastrophic predictions, and anxious feelings, about the PES procedure. A review of published literature suggests that uncertainty about trial procedures are a common barrier to participation for patients groups and non-clinical samples (Ross, Grant, Counsell, Gillespie, Russell, & Prescott, 1999; Sanderson, in preparation). Negative predictions are rarely challenged as men continue to avoid participating in RHTs. However, when men do take part in a RHT, as in this study, catastrophic predictions are modified and anxiety reduces. Catastrophic predictions seemed to be triggered by an uncertainty about the trial procedure, with participants reporting beliefs that the procedure would be intrusive, medical and socially awkward. It also seems that underlying the feelings of anxiety was a threat to participants' masculinity, and a sense of inadequacy. Inhorn (2004) suggests that sub fertility and erectile dysfunction are seen as particularly emasculating. A fear of 'failure' and the resulting anxiety seemed to influence the participants' perceived ability to 'perform', therefore becoming a vicious cycle.

Limitations and future research

Due to the retrospective nature of the study, men's accounts of RHTs were likely to be influenced by their experience of the PES. Although this allowed for a detailed account of experience of PES participation, it is uncertain if these findings can be generalised to other RHTs, or to men who have not taken part in a RHT. Due to the culture-specific and idiosyncratic meanings of masculinity and altruism, definitions of these concepts were not provided to participants. Therefore, participants explored their own experiences and meanings of the PES, masculinity and altruism. Although consistent

themes were found across participants in this study, further research with a varied sample of male participants, on different RHTs, is needed.

Recommendations from study 1 and 2

Recommendations for future RHT recruitment strategies can be made from the results of study one and two. Altruism was a significant predictor and most frequent reason for PES participation, given by participants in study 1. Future clinical trials could emphasise the altruistic elements of participation in recruitment. Psychological literature on increasing altruistic behaviours could guide recruitment strategies. For example, highlighting psychological concepts (such as the bystander effect) that serve as barriers to helping behaviours have been shown to increase the behaviour (Beaman, Barnes, Klentz, & McQuirk, 1978). Recruitment advertisements could stress the importance of the individual to the outcome of the trial and give men an opportunity to feel proud of undertaking a worthwhile cause, or to display their 'moral character'. Promoting the benefits of participation, increasing empathy for the purpose of RHTs, and highlighting the importance of each individual to the outcome, are likely to increase men's altruistic tendencies (Bateson, 1991). However, careful consideration should be given to ensure that participation is perceived more as an 'important moral act' than an 'emasculate concern about one's own health'.

Overall, participants in both studies did not seem to think that masculinity affected their willingness to take part in the PES. However, the dimension of social and cultural roles remained a significant predictor of PES participation. Expectations of men to conform to socio-cultural roles and the use of other men's behaviour as a guide or reference could aid recruitment. Future recruitment strategies could target groups of men, such as sports teams or societies, to establish confidence that participation is socially accepted.

Participants' interests influence their willingness to enter a RHT and differences between demographic groups may be due to different interests. For example, younger males with fewer children in this study may have been more willing to enter the PES due to interest in fertility and conception. Therefore, tailoring trial recruitment advertisements to specific demographic groups may improve recruitment rates. Recruitment may also be improved by changing the practice of RHTs; such as providing more detailed information about the process and rationale of a trial, moving location away from the 'women's and children' hospital', allowing more flexible drop in times, increasing financial incentives and providing travel expenses.

Stigma about masturbation and RH in general was found to be a key reason not to participate in the PES. By challenging beliefs about stigma associated with RHTs, or facilitating methods of coping or overcoming stigma, it is likely that more males will consider participation. Such methods could include moving trials, if appropriate, to more accessible geographical and service locations, as mentioned above. Exposure to RHTs through videos or information centres, at neutral venues, may also help to reduce stigma.

Recruiting men in groups and informing them more about the procedure, may also help to reduce negative predictions about RHTs. For example, specific explanations could be given about the type of procedure, to provide reassurance about privacy, and where applicable dispelling myths about invasive medical procedures. Facilitating popular coping strategies, such as humour and peer support, should also help participants to manage feelings such as anxiety and awkwardness. It is for future RHT conductors to assess the effectiveness of these recommendations.

Conclusion

Study 1 tested the relationship between masculinity, altruism and reproductive health trial participation. Altruism, but not masculinity, significantly predicted a man's willingness to enter a trial. Study 1 was limited by a quantitative design and the complex relationships between masculinity, altruism and RHT participation could not be fully explored.

Study 2 provided an interpretative phenomenological analysis of men's responses to a semi-structured interview, about the experience of taking part in a reproductive health trial. Three super-ordinate themes were developed, including; a conflict in decision making between doing a worthwhile act and the perceived stigma associated with openly discussing and participating in reproductive health trials; the anxiety associated with 'performing' for a trial and a threat to masculinity; and humour and coping strategies to help manage awkward situations. Findings were discussed in relation to previous literature and recommendations to future researchers are made.

List of abbreviations

RH – Reproductive Health

RHT – Reproductive Health Trial

PES – Pre-Ejaculatory Fluid Study

MQ – Perceived Masculinity Questionnaire

AQ – Self-Report Altruism Scale

Declaration of interests

The author had no competing interests.

KEYWORDS: Male, Reproduction, Trials, Masculinity, Altruism

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PART THREE:

Appendices

Appendix 1

Guidelines for authors for the journal 'Trials'

There is no explicit limit on the length of articles submitted, but authors are encouraged to be concise. There is no restriction on the number of figures, tables or additional files that can be included with each article online. Figures and tables should be sequentially referenced. Authors should include all relevant supporting data with each article.

Review articles

Review articles are summaries of recent insights in specific research areas within the scope of *Trials*. Key aims of reviews are to provide systematic and substantial coverage of mature subjects, evaluations of progress in specified areas, and/or critical assessments of emerging technologies.

Manuscript sections for Review articles

Manuscripts for Review articles should be divided into the following sections:

- Title page
- Abstract
- Review
- Conclusions
- List of abbreviations used (if any)
- Competing interests
- Authors' contributions
- Acknowledgements
- References
- Figure legends (if any) – see Figure legends section in main document
- Tables and captions (if any) – see Tables section in main document
- Description of additional data files (if any) – see Additional files section in main document

Title page

This should list the title of the article, the full names, institutional addresses, and email addresses for all authors. The corresponding author should also be indicated.

Abstract

This should not exceed 350 words. Please do not use abbreviations or cite references in the abstract.

Review

This should contain the body of the article, and may also be broken into subsections with short, informative headings.

Conclusions

This should state clearly the main conclusions of the Review and give a clear explanation of their importance and relevance.

List of abbreviations

If abbreviations are used in the text, either they should be defined in the text where first used, or a list of abbreviations can be provided, which should precede the competing interests and authors' contributions.

Competing interests

A competing interest exists when your interpretation of data or presentation of information may be influenced by your personal or financial relationship with other people or organizations. Authors should disclose any financial competing interests but also any non-financial competing interests that may cause them embarrassment were they to become public after the publication of the manuscript.

Non-financial competing interests

Are there any non-financial competing interests (political, personal, religious, ideological, academic, intellectual, commercial or any other) to declare in relation to this manuscript? If so, please specify.

If you are unsure as to whether you or one of your co-authors has a competing interest, please discuss it with the editorial office.

Authors' contributions

In order to give appropriate credit to each author of a paper, the individual contributions of authors to the manuscript should be specified in this section.

An "author" is generally considered to be someone who has made substantive intellectual contributions to a published study. To qualify as an author one should 1) have made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) have been involved in drafting the manuscript or revising it critically for important intellectual content; and 3) have given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.

We suggest the following kind of format (please use initials to refer to each author's contribution): AB carried out the molecular genetic studies, participated in the sequence alignment and drafted the manuscript. JY carried out the immunoassays. MT participated in the sequence alignment. ES participated in the design of the study and performed the statistical analysis. FG conceived of the study, and participated in its design and coordination and helped to draft the manuscript. All authors read and approved the final manuscript.

All contributors who do not meet the criteria for authorship should be listed in an acknowledgements section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chair who provided only general support.

Authors' information

You may choose to use this section to include any relevant information about the author(s) that may aid the reader's interpretation of the article, and understand the standpoint of the author(s). This may include details about the authors' qualifications, current positions they hold at institutions or societies, or any other relevant background information. Please refer to authors using their initials. Note this section should not be used to describe any competing interests.

Acknowledgements

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The role of a medical writer must be included in the acknowledgements section, including their source(s) of funding.

Authors should obtain permission to acknowledge from all those mentioned in the Acknowledgements.

Please list the source(s) of funding for the study, for each author, and for the manuscript preparation in the acknowledgements section. Authors must describe the role of the funding body, if any, in study design; in the collection, analysis, and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication.

References

All references must be numbered consecutively, in square brackets, in the order in which they are cited in the text, followed by any in tables or legends. Reference citations should not appear in titles or headings. Each reference must have an individual reference number. Please avoid excessive referencing. If automatic numbering systems are used, the reference numbers must be finalized and the bibliography must be fully formatted before submission.

Only articles and abstracts that have been published or are in press, or are available through public e-print/preprint servers, may be cited; unpublished abstracts, unpublished data and personal communications should not be included in the reference list, but may be included in the text and referred to as "unpublished data", "unpublished observations", or "personal communications" giving the names of the involved researchers. Notes/footnotes are not allowed. Obtaining permission to quote personal communications and unpublished data from the cited author(s) is the responsibility of

the author. Journal abbreviations follow Index Medicus/MEDLINE. Citations in the reference list should contain all named authors, regardless of how many there are.

Examples of the *Trials* reference style are shown below. Please take care to follow the reference style precisely; references not in the correct style may be retyped, necessitating tedious proofreading.

Links

Web links and URLs should be included in the reference list. They should be provided in full, including both the title of the site and the URL, in the following format: **The Mouse Tumor Biology Database** [http://tumor.informatics.jax.org/mtbwi/index.do]

Trials reference style

Style files are available for use with popular bibliographic management software:

- BibTeX
- EndNote style file
- Reference Manager

Article within a journal

1. Koonin EV, Altschul SF, Bork P: **BRCA1 protein products: functional motifs.** *Nat Genet* 1996, **13:**266-267.

Article within a journal supplement

2. Orengo CA, Bray JE, Hubbard T, LoConte L, Sillitoe I: **Analysis and assessment of ab initio three-dimensional prediction, secondary structure, and contacts prediction.** *Proteins* 1999, **43**(Suppl 3):149-170.

In press article

3. Kharitonov SA, Barnes PJ: **Clinical aspects of exhaled nitric oxide.** *Eur Respir J*, in press.

Published abstract

4. Zvaifler NJ, Burger JA, Marinova-Mutafchieva L, Taylor P, Maini RN: **Mesenchymal cells, stromal derived factor-1 and rheumatoid arthritis [abstract].** *Arthritis Rheum* 1999, **42:**s250.

Article within conference proceedings

5. Jones X: **Zeolites and synthetic mechanisms.** In *Proceedings of the First National Conference on Porous Sieves: 27-30 June 1996; Baltimore.* Edited by Smith Y. Stoneham: Butterworth-Heinemann; 1996:16-27.

Book chapter, or article within a book

6. Schnepf E: **From prey via endosymbiont to plastids: comparative studies in dinoflagellates.** In *Origins of Plastids. Volume 2.* 2nd edition. Edited by Lewin RA. New York: Chapman and Hall; 1993:53-76.

Whole issue of journal

7. Ponder B, Johnston S, Chodosh L (Eds): **Innovative oncology.** In *Breast Cancer Res* 1998, **10:**1-72.

Whole conference proceedings

8. Smith Y (Ed): *Proceedings of the First National Conference on Porous Sieves: 27-30 June 1996; Baltimore.* Stoneham: Butterworth-Heinemann; 1996.

Complete book

9. Margulis L: *Origin of Eukaryotic Cells.* New Haven: Yale University Press; 1970.

Monograph or book in a series

10. Hunninghake GW, Gadek JE: **The alveolar macrophage.** In *Cultured Human Cells and Tissues.* Edited by Harris TJR. New York: Academic Press; 1995:54-56. [Stoner G (Series Editor): *Methods and Perspectives in Cell Biology,* vol 1.]

Book with institutional author

11. Advisory Committee on Genetic Modification: *Annual Report.* London; 1999.

PhD thesis

12. Kohavi R: **Wrappers for performance enhancement and oblivious decision graphs.** *PhD thesis.* Stanford University, Computer Science Department; 1995.

Appendix 2

Data extraction form

Study Title	
Author(s) and Year of Publication	
Participants	
Objective	
Methodology	
Inclusion Criteria	
Results	
Reasons for participation	

Appendix 3

Quantitative quality assessment items (adapted from Downs & Black, 1998)

1. Is the hypothesis, aim or objective of the study clearly described?

2. Are the main outcomes to be measured clearly described in the Introduction or Methods section?

3. Are the characteristics of the patients included in the study clearly described?

5. Are the distributions of principal confounders in each group of subjects to be compared clearly described?

6. Are the main findings of the study clearly described?

7. Does the study provide estimates of the random variability in the data for the main outcomes?

8. Have all-important adverse events that may be a consequence of the intervention been reported?

9. Have the characteristics of patients lost to follow-up been described?

10. Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?

11. Were the subjects **asked** to participate in the study representative of the entire population from which they were recruited?

12. Were those subjects who were prepared to participate representative of the entire population from which they were recruited?

13. Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive?

16. If any of the results of the study were based on "data dredging", was this made clear?

17. In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls?

18. Were the statistical tests used to assess the main outcomes appropriate?

20. Were the main outcome measures used accurate (valid and reliable)?

22. Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time?

26. Were losses of patients to follow-up taken into account?

27. Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?

Appendix 4

The 'Quality Framework' by Spencer, Ritchie, Lewis, & Dilon, (2003)

FRAMEWORK FOR ASSESSING QUALITATIVE EVALUATIONS[3]

Study being appraised: .....

	a) Appraisal questions	b) Quality indicators (possible features for consideration)	c) Notes on study being appraised
1 FINDINGS	How credible are the findings?	Findings/conclusions are supported by data/study evidence *(i.e. the reader can see how the researcher arrived at his/her conclusions; the 'building blocks' of analysis and interpretation are evident)* Findings/conclusions 'make sense'/have a coherent logic Findings/conclusions are resonant with other knowledge and experience *(this might include peer or member review)* Use of corroborating evidence to support or refine findings (i.e. other data sources have been used to examine phenomena; other research evidence has been evaluated: see also Q14)	
2 FINDINGS	How has knowledge/ understanding been extended by the research?	Literature review (where appropriate) summarising knowledge to date/key issues raised by previous research Aims and design of study set in the context of existing knowledge/ understanding; identifies new areas for investigation *(for example, in relation to policy/practice/substantive theory)* Credible/clear discussion of how findings have contributed to knowledge and understanding *(e.g. of the policy, programme or theory being reviewed)*; might be applied to new policy developments, practice or theory Findings presented or conceptualised in a way that offers new insights/alternative ways of thinking Discussion of limitations of evidence and what remains unknown/unclear or what further information/research is needed	

[3] For those wishing to read further about qualitative and evaluative research methods a short list of useful references can be found at the end.

	a) Appraisal questions	b) Quality indicators (possible features for consideration)	c) Notes on study being appraised
3 FINDINGS	How well does the evaluation address its original aims and purpose?	Clear statement of study aims and objectives; reasons for any changes in objectives Findings clearly linked to the purposes of the study – and to the initiative or policy being studied Summary or conclusions directed towards aims of study Discussion of limitations of study in meeting aims *(e.g. are there limitations because of restricted access to study settings or participants, gaps in the sample coverage, missed or unresolved areas of questioning; incomplete analysis; time constraints?)*	
4 FINDINGS	Scope for drawing wider inference – how well is this explained?	Discussion of what can be generalised to wider population from which sample is drawn/case selection has been made Detailed description of the contexts in which the study was conducted to allow applicability to other settings/contextual generalities to be assessed Discussion of how hypotheses/ propositions/findings may relate to wider theory; consideration of rival explanations Evidence supplied to support claims for wider inference *(either from study or from corroborating sources)* Discussion of limitations on drawing wider inference *(e.g. re-examination of sample and any missing constituencies: analysis of restrictions of study settings for drawing wider inference)*	
5 FINDINGS	How clear is the basis of evaluative appraisal?	Discussion of how assessments of effectiveness/evaluative judgements have been reached *(i.e. whose judgements are they and on what basis have they been reached?)* Description of any formalised appraisal criteria used, when generated and how and by whom they have been applied Discussion of the nature and source of any divergence in evaluative appraisals Discussion of any unintended consequences of intervention, their impact and why they arose	

	a) Appraisal questions	b) Quality indicators (possible features for consideration)	c) Notes on study being appraised
6 DESIGN	How defensible is the research design?	Discussion of how overall research strategy was designed to meet aims of study Discussion of rationale for study design Convincing argument for different features of research design *(e.g. reasons given for different components or stages of research; purpose of particular methods or data sources, multiple methods, time frames etc.)* Use of different features of design/data sources evident in findings presented Discussion of limitations of research design and their implications for the study evidence	
7 SAMPLE	How well defended is the sample design/ target selection of cases/documents?	Description of study locations/areas and how and why chosen Description of population of interest and how sample selection relates to it *(e.g. typical, extreme case, diverse constituencies etc.)* Rationale for basis of selection of target sample/settings/documents *(e.g. characteristics/features of target sample/settings/documents, basis for inclusions and exclusions, discussion of sample size/number of cases/setting selected etc.)* Discussion of how sample/selections allowed required comparisons to be made	
8 SAMPLE	Sample composition/case inclusion – how well is the eventual coverage described?	Detailed profile of achieved sample/case coverage Maximising inclusion *(e.g. language matching or translation; specialised recruitment; organised transport for group attendance)* Discussion of any missing coverage in achieved samples/cases and implications for study evidence *(e.g. through comparison of target and achieved samples, comparison with population etc.)* Documentation of reasons for non-participation among sample approached/non-inclusion of selected cases/documents Discussion of access and methods of approach and how these might have affected participation/coverage	

	a) Appraisal questions	b) Quality indicators (possible features for consideration)	c) Notes on study being appraised
9 DATA COLLECTION	How well was the data collection carried out?	Discussion of: • who conducted data collection • procedures/documents used for collection/recording • checks on origin/status/authorship of documents Audio or video recording of interviews/discussions/conversations *(if not recorded, were justifiable reasons given?)* Description of conventions for taking fieldnotes *(e.g. to identify what form of observations were required/to distinguish description from researcher commentary/analysis)* Discussion of how fieldwork methods or settings may have influenced data collected Demonstration, through portrayal and use of data, that depth, detail and richness were achieved in collection	
10 ANALYSIS	How well has the approach to, and formulation of, the analysis been conveyed?	Description of form of original data *(e.g. use of verbatim transcripts, observation or interview notes, documents, etc.)* Clear rationale for choice of data management method/tool/package Evidence of how descriptive analytic categories, classes, labels etc. have been generated and used *(i.e. either through explicit discussion or portrayal in the commentary)* Discussion, with examples, of how any constructed analytic concepts/typologies etc. have been devised and applied	
11 ANALYSIS	Contexts of data sources – how well are they retained and portrayed?	Description of background or historical developments and social/organisational characteristics of study sites or settings Participants' perspectives/observations placed in personal context *(e.g. use of case studies/vignettes/individual profiles, textual extracts annotated with details of contributors)* Explanation of origins/history of written documents Use of data management methods that preserve context *(i.e. facilitate within case description and analysis)*	

	a) Appraisal questions	b) Quality indicators (possible features for consideration)	c) Notes on study being appraised
12 ANALYSIS	How well has diversity of perspective and content been explored?	Discussion of contribution of sample design/ case selection in generating diversity Description and illumination of diversity/ multiple perspectives/ alternative positions in the evidence displayed Evidence of attention to negative cases, outliers or exceptions Typologies/ models of variation derived and discussed Examination of origins/ influences on opposing or differing positions Identification of patterns of association/ linkages with divergent positions/ groups	
13 ANALYSIS	How well has detail, depth and complexity (i.e. richness) of the data been conveyed?	Use and exploration of contributors' terms, concepts and meanings Unpacking and portrayal of nuance/ subtlety/ intricacy within data Discussion of explicit and implicit explanations Detection of underlying factors/ influences Identification and discussion of patterns of association/ conceptual linkages within data Presentation of illuminating textual extracts/ observations	
14 REPORTING	How clear are the links between data, interpretation and conclusions – i.e. how well can the route to any conclusions be seen?	Clear conceptual links between analytic commentary and presentations of original data *(i.e. commentary and cited data relate; there is an analytic context to cited data, not simply repeated description)* Discussion of how/ why particular interpretation/ significance is assigned to specific aspects of data – with illustrative extracts of original data Discussion of how explanations/ theories/ conclusions were derived – and how they relate to interpretations and content of original data *(i.e. how warranted)*; whether alternative explanations explored Display of negative cases and how they lie outside main proposition/ theory/ hypothesis etc.; or how proposition etc. revised to include them	

	a) Appraisal questions	b) Quality indicators (possible features for consideration)	c) Notes on study being appraised
15 REPORTING	How clear and coherent is the reporting?	Demonstrates link to aims of study/research questions Provides a narrative/story or clearly constructed thematic account Has structure and signposting that usefully guide reader through the commentary Provides accessible information for intended target audience(s) Key messages highlighted or summarised	
16 REFLEXIVITY & NEUTRALITY	How clear are the assumptions/theoretical perspectives/values that have shaped the form and output of the evaluation?	Discussion/evidence of the main assumptions/hypotheses/theoretical ideas on which the evaluation was based and how these affected the form, coverage or output of the evaluation *(the assumption here is that no research is undertaken without some underlying assumptions or theoretical ideas)* Discussion/evidence of the ideological perspectives/values/philosophies of research team and their impact on the methodological or substantive content of the evaluation *(again, may not be explicitly stated)* Evidence of openness to new/alternative ways of viewing subject/theories/assumptions *(e.g. discussion of learning/concepts/ constructions that have emerged from the data; refinement restatement of hypotheses/theories in light of emergent findings; evidence that alternative claims have been examined)* Discussion of how error or bias may have arisen in design/data collection/analysis and how addressed, if at all Reflections on the impact of the researcher on the research process	

	a) Appraisal questions	b) Quality indicators (possible features for consideration)	c) Notes on study being appraised
17 ETHICS	What evidence is there of attention to ethical issues?	Evidence of thoughtfulness/sensitivity about research contexts and participants Documentation of how research was presented in study settings/to participants *(including, where relevant, any possible consequences of taking part)* Documentation of consent procedures and information provided to participants Discussion of confidentiality of data and procedures for protecting Discussion of how anonymity of participants/sources was protected Discussion of any measures to offer information/advice/services etc. at end of study *(i.e. where participation exposed the need for these)* Discussion of potential harm or difficulty through participation, and how avoided	
18 AUDITABILITY	How adequately has the research process been documented?	Discussion of strengths and weaknesses of data sources and methods Documentation of changes made to design and reasons; implications for study coverage Documentation and reasons for changes in sample coverage/data collection/analytic approach; implications Reproduction of main study documents *(e.g. letters of approach, topic guides, observation templates, data management frameworks etc.)*	

Appendix 5: Quantitative quality assessment scores

	Quantitative quality assessment items																	
Study No. Author	1	2	3	5	6	7	9	10	11	12	13	16	17	18	20	22	27	Total
1. Trauth et al (2000)	1	1	1	1	1	1	1	1	1	0	1	1	0	1	0	1	1	14
2. Carlsson et al (2006)	1	1	1	1	1	1	1	1	1	0	1	1	0	1	1	1	1	15
3. Williams et al (2006)	1	1	1	1	1	1	0	1	1	0	1	1	0	1	0	1	1	13
4. Bost (2005)	1	1	0	0	1	0	0	0	0	0	1	1	1	1	0	1	0	8
5. Feveile et al (2007)	1	1	1	1	1	1	0	1	1	0	1	1	1	1	1	1	1	15
6. Spencer et al (2004)	1	1	0	0	1	0	1	0	0	0	1	1	1	1	0	1	0	9
7. Beebe et al (2008)	1	1	1	1	1	1	0	1	1	0	1	1	0	1	0	1	1	13
8. Tishler et al (2007)	1	1	1	1	1	1	1	1	0	0	1	1	1	1	1	1	0	14
9. Kennedy et al (2007)	1	1	0	0	1	1	0	1	0	0	1	1	1	1	1	1	1	12
12. Ohmann et al (2004)	1	1	1	1	1	1	1	1	0	0	1	1	1	1	0	1	1	14
Total	10	10	7	7	10	8	5	8	5	0	10	10	6	10	4	10	7	-

Appendix 6

Inter-rater quantitative quality assessment scores

	Quantitative quality assessment items																		
Study No. author	1	2	3	5	6	7	9	10	11	12	13	16	17	18	20	22	27	Total	Inter-rater (Kappa)
1. Trauth et al (2000)	1	1	1	1	1	1	0	1	1	0	1	1	1	1	0	1	1	14	0.60
2. Carlsson et al (2006)	1	1	1	1	1	1	1	1	1	0	1	1	0	1	1	1	1	15	0.77
3. Williams et al (2006)	1	1	1	1	1	1	o	1	1	0	1	1	1	1	0	1	1	14	0.82
4. Bost (2005)	1	0	0	0	1	0	0	0	0	0	1	1	1	0	0	1	0	6	0.76
8. Tishler et al (2007)	1	1	1	1	1	1	1	1	0	0	1	1	1	1	1	1	0	14	1.00
9. Kennedy et al (2007)	1	1	0	0	1	1	0	1	0	0	0	1	1	1	1	1	1	11	0.87
12. Ohmann et al (2004)	1	1	1	1	1	1	1	1	0	0	1	1	1	1	0	1	1	14	1.00
Total	7	6	5	5	7	5	4	6	3	0	6	7	6	6	3	7	5	-	0.83

Appendix 7

Qualitative quality assessment scores

Study No. Author	Qualitative quality assessment items																		
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	Total
10. Dixon Woods et al (2009)	1	1	1	1	1	1	1	1	0	0	1	1	1	1	1	1	0	0	14
11. BeLue et al (2006)	1	1	1	0	1	1	1	1	1	1	1	0	1	1	1	0	1	0	14
11. Inter rater: BeLue et al (2006)	1	1	1	0	1	1	1	1	1	1	1	0	1	1	1	0	1	0	14

Appendix 8

Guidelines for authors for the journal of Human Reproduction

Scope

Human Reproduction publishes full length, peer reviewed papers reporting original research, as well as opinions, debates and clinical case reports of outstanding originality and importance. Mini-reviews forming part of the 'Developments in Reproductive Biology and Medicine' series are also occasionally published. These articles aim at summarizing concisely particularly important and rapidly-developing areas of reproductive medicine for which not enough has been published to enable more substantive reviews to be written. The majority of 'Developments' reviews will originate from the journal's Associate Editors but uninvited contributions are also welcomed.

Papers should be within the recognized broad scope of human reproductive biology and reproductive medicine. This includes relevant scientific and clinical aspects of reproductive physiology and pathology, reproductive endocrinology and endocrine therapies. It also includes andrology, contraception, early pregnancy, embryo development, ethical issues, fertilization, gametogenesis, genetic screening (first trimester) , genetic diagnosis (pre-implantation), gonadal function, implantation, infectious diseases, menstrual disorders, psycho-social issues, reproductive genetics, reproductive surgery, reproductive oncology, reproductive epidemiology, and stem cell research. Research which would be classified as clearly in the fields of obstetrics or gynaecological oncology will not normally be published.

Manuscript length

Papers should be of a length appropriate for the amount of information they contain. Failure to restrict the length of manuscripts, especially Introduction and Discussion sections, can negatively influence the reviewers' and the editor's decisions.

Style

Manuscripts should be written using clear and concise English, with English standard spelling and conventions. Non English speaking authors are advised to enlist the assistance of a native English speaker, familiar with biomedical terminology. The editors reserve the right to return without review manuscripts that can not be adequately

assessed due to a poor standard of English. For Biochemical and Bacterial terminology follow the International Union of Pure and Applied Chemistry (IUPAC) and International Union of Biochemistry and Molecular Biology (IUBMB) recommendations Genotypes must be italicized; phenotypes should not.

Units of measurement and abbreviations

Units of measurement should be in Systéme International (SI) units and those recommended by the IUPAC should be used wherever possible. Standard units of measurements and chemical symbols of elements may be used without definition in the body of the paper. Abbreviations should be given in brackets after their first mention in the text, and used thereafter. For centrifugation rates give g values rather than rpm, as this will vary according to rotor diameter.

Format

Double spacing on one side of the paper only. Number each page top right. Number lines. Avoid underlining. Differentiate clearly letters O, I and numbers 0, 1. Ensure unusual symbols are written clearly.

Structure (listed in order of appearance in the published manuscript)

Title

Should not exceed 25 words and should be specific and informative.

Running title

Should not exceed 50 characters.

Authors

Give initials and family name of all authors. Declaration of Author's roles is required at submission and this information will be included after the discussion, see below. (Please refer to the section 'To accompany manuscript at submission' above for more details regarding authorship)"

Address

The department, institution, city and country should be given with postal code for each

author. An e mail address will be published for the corresponding author, who should be clearly identified. Current addresses should be provided for all authors.

Abstract

The abstract should be a single paragraph which clearly summarizes the findings of the manuscript. Note that online abstracts are published for viewing in isolation to the main body of the manuscript and should be self explanatory. The following structured headings should be used to divide the text of abstracts: BACKGROUND, METHODS, RESULTS and CONCLUSIONS. All papers should clearly describe within the BACKGROUND section the background and objective of the study and within the METHODS section the design, setting, patients, interventions and main outcome measures should be described. Where multiple methodologies have been used, these and the results obtained can be presented in sequence in a combined METHODS and RESULTS section. Mention of the study's single most important limitation should be made in the CONCLUSION section of the abstract. Citations should not appear in the abstract. A structured abstract format is not applicable to Debates, Opinions and Case Reports.

Key words

Up to five key words must be supplied by the author. The key words, together with the title and abstract, are used for online searches. They should therefore be specific and relevant to the paper.

Introduction

The introduction should be limited to the specific background necessary to show the importance and context of the current study. The objective of the study should be clearly stated in the final paragraph of the Introduction.

Materials and methods

The names, town and country of origin of all suppliers should be included.

Results

Unnecessary overlap between tables, figures and text should be avoided.

Discussion

The discussion should begin with a succinct statement of the principal findings, outline the strengths and weaknesses of the study, discuss the findings in relation to other studies, provide possible explanations and indicate questions which remain to be answered in future research.

Author's roles Please give details for the contributions of each of the authors, including participation in study design, execution, analysis, manuscript drafting and critical discussion.

Acknowledgements

Personal acknowledgements should precede those of institutions or agencies.

Funding

With respect to funding of research, in line with the World Association of Medical Editors (WAME) guidelines, http://www.wame.org/wamestmt.htm#fundres the journal considers it the responsibility of the author to protect the integrity of the research record from bias related to the source of funding by fully declaring all sponsorships, the roles played by sponsors in the research as well as institutional affiliations and relevant financial ties. These should be listed in the manuscript after the 'Acknowledgements'.

Reference citations within the text

Authors are responsible for the accuracy of the references. Each reference should be cited by author and date. If there are two authors please list both, if more than two please use first author then et al. Permission to cite personal communications (J.Smith, personal communication) should be obtained by the corresponding author. Unpublished data should be cited as (unpublished data) and should not be included in the reference list. Either of the above should be used only when essential.

References to papers accepted for publication, but not yet published, should be cited as such in the reference list e.g. Bloggs A (2007) In vitro fertilization. Hum Reprod, in press.

Reference list

Please use the following style. Note that correct punctuation and journal abbreviations must be used in order to run the search programs used to edit the manuscript. Incorrectly types references take a lot of time to correct, for which we reserve the right to charge. Up to 10 authors should be included after which et al. should be used. Refer to the following examples.

Authors. Title. *Journal* date; issue: pg-pg

Biggers JD and McGinnis LK. Evidence that glucose is not always an inhibitor of mouse preimplantation development in vitro. *Hum Reprod* 2001:**16**:153-163.

Gekas J, Thepot F, Turleau C, Siffroi JP, Dadaoune JP, Briault S, Rio M, Bourouillou G, Carre Pigeon F, Wasels R et al. Chromosomal factors of infertility in candidate couples for ICSI: an equal risk of constitutional aberrations in women and men. *Hum Reprod* 2001;**16**: 82-90.

Elliot WH and Elliot DC. Biochemistry and Molecular Biology. 2nd edn, 2001.Oxford University Press, Oxford, UK.

Warren MA, Li TC and Klentzeris D. Cell biology of the endometrium: histology, cell types and menstrual changes. In Chard T and Grudzinskas JG (eds) The Uterus. 1994. Press Syndicate of the University of Cambridge, Cambridge, UK, pp.94-125.

Tables

Each table should be numbered consecutively with Roman numerals. Please avoid complex constructions. Each item of data should be in a separate cell and should be produced using Word or Excel format. Each table should be self explanatory and include a brief descriptive title. Footnotes to the table indicated by superscript lowercase letters are acceptable but should not include extensive experimental detail. Reference to the tables in the text should be sequential (ie Table I, II etc). Do not include more tables than is absolutely necessary – non-essential tables may be judged as being suitable for online-only publication.

Figure legends

Each legend must be self contained, with all symbols and abbreviations used in the figure defined.

Figures

Full instructions on preparing the figures are available as part of the online submission instructions. Please follow these instructions carefully as failure to do so will delay publication of your manuscript (please note: the editors reserve the right to charge for extensive changes). In preparing graphs authors should avoid background tints and 3D effects and maintain a consistent label size and aspect ratio (the x/y axis ratio) throughout a paper. Figure and axes titles should be clear and NOT in bold text. Do not include more figures than is absolutely necessary – non-essential figures may be judged as being suitable for online-only publication.

Appendix 9

Ethical approval letter

(R & D approval not required due to the use of a non-clinical sample)

POSTGRADUATE MEDICAL INSTITUTE
(IN ASSOCIATION WITH HULL YORK MEDICAL SCHOOL)

DL/JBK

6 April 2009

Mr C Sanderson
Department of Clinical Psychology
Hertford Building
The University of Hull
Cottingham Road
HULL HU6 7RX

Dear Chris

Thank you for attending the Faculty Ethics Committee meeting on Tuesday, 31 March 2009 and explaining so coherently your research proposal to the committee. I am pleased to report that the committee approved your proposal with the following recommendations;

1. Clarification is required on the consent form regarding the term 'convenience sampled study'
2. The documentation needs to reflect that this research is being conducted through the Postgraduate Medical Institute (PGMI) and not HYMS.

May I take this opportunity of wishing you every success with your research.

Yours sincerely

DOMINIC LAM
Chair – PGMI Ethics Committee

Professor Nicholas D Stafford MB FRCS
Director – Postgraduate Medical Institute
Postgraduate Medical Institute, Hertford Building (Room 203)
The University of Hull
Hull, HU6 7RX, UK
T: +44 (0) 1482 465348/464213
F: +44 (0) 1482 463421
N.D.Stafford@hull.ac.uk

Appendix 10

Internet advertisement picture used for survey recruitment

Appendix 11

Information sheet

Masculinity, Altruism and Participation in Male Reproductive Health Studies

INFORMATION SHEET

Thank you for showing an interest in this project. Please read this information sheet carefully before deciding whether to take part. If you decide not to take part, there will be no disadvantage to you of any kind and we thank you for considering our request.

What is the Aim of the Project?

The aim of this project is to measure participant's responses on a masculinity and altruism questionnaire and assess if these measures are related on a participants decision to participate in a reproductive health study.

Why have you been asked?

You have been asked to participate in this study as you are male.

What will you have to do?

You will be asked to fill out a questionnaire and if you would like to consent to take part in a reproductive health experiment. This should take about 10 minutes. You can fill out only the online questionnaire and then afterwards choose if you would like to participate in a reproductive health study and an interview about your experiences. Potential participants are advised that they can complete the online questionnaire only and do not have to take part in the reproductive health study.

Please be aware that you may decide not to take part in the project without any disadvantage to yourself of any kind.

Can I change my mind and withdraw from the project?

You may withdraw from participation in the project at any time whilst filling out the questionnaire and without any disadvantage to yourself of any kind. Once the questionnaire has been completed, the data is stored anonymously and therefore cannot be withdrawn.

What data or information will be collected and what use will be made of it?

Responses from the questionnaires and information such as your age, education and family status will be collected anonymously. No names or identifiable information will be recorded.

All information collected will be compared together to assess if it has any relevance to men's choice to participate in a reproductive health experiment.

The information will be used to see if certain personality traits influence a men's decision to participate in a reproductive health study. This may help to make reproductive health studies for males more accessible and therefore increase participation. Higher participation rates will inevitably help to increase the understanding of male reproductive health therefore facilitating the development of new interventions for infertility, sexual dysfunction and sexually transmitted diseases.

The results of the project may be published but participants can be assured of 100% anonymity.

What if I have any questions?

If you have any questions about our project, either now or in the future, please feel free to contact:

Chris Sanderson

The Department of Clinical Psychology

Hertford Building

The University of Hull

Cottingham Road

07852134817

C.J.Sanderson@2007.Hull.ac.uk

This project has been reviewed and approved by the Post Graduate Medical Institute Ethics Committee, The University of Hull.

Appendix 12

Consent form

Consent Form

Participation in this project is voluntary.

You are free to withdraw from this project at any time without any disadvantage.

The results of this project may be published but participants can be assured of 100% anonymity.

Chris Sanderson
Trainee Clinical Psychologist
Department of Clinical Psychology
The University of Hull
Email: C.J.Sanderson@2007.Hull.ac.uk

This project has been reviewed and approved by the Post Graduate Medical Institute Ethics Committee, The University of Hull.

***1. Please read the information given above**

- I agree to take part in the survey

***2. You must be over 18 to take part in this study.**

- I am over 18

Appendix 13

Internet survey questions converted to text format

Survey items were randomised for the study and dimension titles removed. Dimension titles are included here to report each dimensions items on the MQ.

What is your gender?
- Male / Female (only males continue)

1. What is your age?
- 18-27
- 28-37
- 38-47
- 48-57
- 58-67
- 67 +

2. What is the highest level of educational qualifications you achieved / have achieved so far?
- SAT's (year 9)
- GCSE's
- NVQ
- Vocational course / apprentice
- University Graduate
- Masters / PhD

3. Where are you from?
- United Kingdom
- Europe
- Africa
- Asia
- Americas
- Australasia

4. How would you class your ethnicity?
- White
- Mixed
- Asian
- Black
- Chinese
- Other

5. What is your relationship status?
- Single
- In a long term relationship / married
- Divorced
- widowed

6. Do you have any children?

- No
- Yes

7. How religious do you say you are?
Not at all 1(A) 2(B) 3(C) religious | | | 4(D) 5(E) | 6(F) 7(G) Strongly religious

DIMENSION 1: Physiological Energy—Arousal. Tension, and Aggressive Tendencies

8. In terms of your experiences in society, how desirable has it been for you to be aggressive?
Strongly 1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G) Strongly
undesirable desirable

9. In terms of your experiences in society, how desirable has it been for you to be assertive?
Strongly 1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G) Strongly
Undesirable desirable

10. In terms of your experiences in society, how desirable has it been for you to be competitive?
Strongly 1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G) Strongly
undesirable desirable

11. In terms of your experiences in society, how desirable has it been for you to be dominant?
Strongly 1(A) 2(B) 3(C) 4(D) 5(F) 6(F) 7(G) Strongly
undesirable desirable

DIMENSION 2: Physical Characteristics—Bodily Shape and Size

12. When you are compared to others of your own sex, how often do you think you are perceived or treated as more **physically muscular** (i.e., taller, stronger) than others of your own sex?
1(A) 2(B) 3(C) 4(D) • 5(E) 6(F) 7(G)
Never Always

13. When you think about how others see and respond to **your own body shape,** how do you think they characterize your body?
Extremely 1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G) Extremely
lean obese

14. When you think about how others hear and respond to **the quality of your voice,** how do you think they characterize it?
Extremely 1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G) Extremely
low-pitched high-pitched

15. When you think about how others hear and respond to **the quality of your voice,** how do you think they characterize it?
Extremely 1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G) Extremely

emotional factual

DIMENSION 3: Gender-Related Socio-cultural Roles

16. How strongly do **you** see yourself as a fan of your favourite sports team (it can be any sport)?
Not at all 1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G) Extremely enthusiastic
enthusiastic

17. How strongly do **your friends** see you as a fan of your favourite sports team (it can be any sport)?
Not at all 1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G) Extremely
enthusiastic enthusiastic

18. During the season, how closely do you follow your favourite sports team (it can be any sport) via any of the following: a) in person or on television, b) on the radio, and/or c) television news or a newspaper?
1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G)
Never Everyday

19. How often do you display your favourite sports team's (it can be any sport) name or insignia at any of the following: a) your place of work, b) where you live, and/or c) on your clothing?
1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G)
Never Always

DIMENSION 4: Idealized Gender

20. When you think about society's definition of the "masculine man" (as it is emerging in television and newspaper advertisements), how powerful do you think this image is?
Extremely 1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G) Extremely
strong weak

21. When you think about the definition of the "masculine man" that is emerging in your local environment or your immediate culture, how powerful do you think this image is?
Extremely 1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G) Extremely strong
weak

22. When you think of your current or most recent sexual partner, regardless of whether or not the partner is male or female, **you** characterize your sexual image and style as:
Less masculine 1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G) More masculine than your partner
than your partner

23. When you think of your current or most recent sexual partner and how other people reacted or responded to you and your partner as a couple, **other people** tended to treat you as:
Less masculine 1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G) More masculine than your partner
than your partner

DIMENSION 5: **Sexual Preference**

24. In terms of your choice of sexual partners, what is your sexual preference?
Always the 1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G) Always the
same sex opposite sex

25. When you think about your last few sexual fantasies (in your dreams and perhaps even in day dreams), were you thinking about the same or opposite sex?
Always the 1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G) Always the
same sex opposite sex

26. When you focus just on what gives you physical satisfaction during sex, to what degree is the sex of your partner important?
Strongly 1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G) Strongly
important unimportant

27. When you focus just on what gives you emotional or psychological pleasure during sex, to what degree is the sex of your partner important?
Strongly 1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G) Strongly
important unimportant

DIMENSION 6: Subjective Gender-Identity

28. When you think of or imagine the sexual role that you generally have of yourself, **you** think of yourself as:
Never 1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G) Highly
masculine masculine

29. When you think of or imagine the sexual role that your friends have of you, **your friends** treat you as:
Never 1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G) Highly
masculine masculine

30. When you think of or imagine the sexual role that your parents have of you, **your parents** treat you as:
Never 1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G) Highly
masculine masculine

31. When you think of or imagine the sexual role that strangers have of you, **strangers** treat you as:
Never 1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G) Highly
Masculine masculine

DIMENSION 7: Gender-Related Age Identity

32. How often do **you** feel as if you are sexually immature?
1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G)
Never Always

33. How often do **others** treat you as sexually immature?
1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G)

Never Always

34. How often do **you** feel as if you are too old to enjoy or engage in sexual relations?
1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G)
Never Always

35. How often do **others** treat you as if you are too old to enjoy or engage in sexual relations?
1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G)
Never Always

DIMENSION 8: Gender-Related Racial and National Identities

36. How often do **you** feel you are restricted sexually because of your race and/or nationality?
1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G)
Never Always

37. How often do **others** treat you as restricted sexually because of your race and/or nationality? 1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G)
Never Always

38. How often do you feel society (e.g., in television and magazine advertising) is restricting you sexually because of your race and/or nationality?
1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G)
Never Always

39. How often do you feel that forces or factors in **your local environment or your immediate culture** are restricting you sexually because of your race and/or nationality?
1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G)
Never Always

DIMENSION 9: Lust

40. How frequently do you want sex?
Less than once a month 1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G) More than once a day

41. How important do you think it is for "romance" (i.e., affection, love, and intimacy) to be established before orgasm?
Not at all 1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G) Very important
important

42. What kind of body stimulation do you prefer when having sex?
Genital 1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G) Full body contact
only contact

43. How much erotic touching or foreplay before orgasm do you prefer?
Very 1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G) Very minimal
extensive

DIMENSION 10: Male Eroticism

44. To what degree do you think society (e.g., in television and magazine advertising) uses a man's weight, muscle tone, and overall physical appearance to determine how masculine or manly a man is?
1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G)
Never Always

45. To what degree do **you** think a man's weight, muscle tone, and overall physical appearance determine how masculine or manly a man is?
1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G)
Never Always

46. To what degree do you think **society** (e.g., in television and magazine advertising) uses a man's grooming (e.g., after shave, cologne, and deodorant), clothes, hair style, and fashion sense to determine how masculine or manly a man is?
1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G)
Never Always

47. To what degree do **you** think a man's grooming (e.g., after shave, cologne, and deodorant), clothes, hair style, and fashion sense determine how masculine or manly a man is?
1(A) 2(B) 3(C) 4(D) 5(E) 6(F) 7(G)
Never Always

Altruism Scale

48. I have helped push a stranger's car out of the snow

49. I have given directions to a stranger

50. I have made change for a stranger

51. I have given money to a charity

52. I have given money to a stranger who needed it (or asked me for it).

53. I have donated goods or clothes to a charity

54. I have done volunteer work for a charity

55. I have donated blood

56. I have helped carry stranger's belongings (books, parcels, etc).

57. I have delayed an elevator and held the door open for a stranger.

58. I have allowed somebody to go ahead of me in a queue (At a bank machine, in the supermarket, etc.)

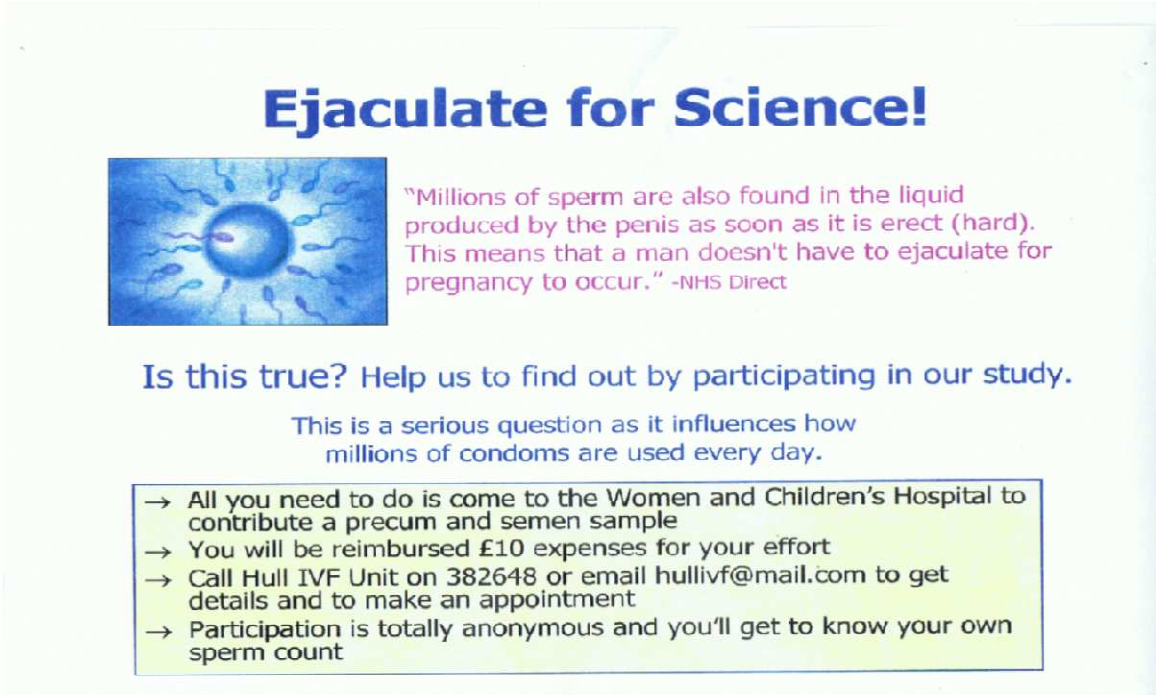
59. I have given a stranger a lift in my car.

60. I have pointed out a clerk's error (in a bank, at the supermarket) in undercharging me for an item.

61. I have let a neighbour whom I didn't know too well borrow an item of some value to me (e.g. a dish, tools, etc).

62. I have bought 'charity' Christmas cards deliberately because I knew it was a good cause.

Pre-ejaculatory fluid study (PES) recruitment poster



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63. Would you be interested in taking part in taking part in this study?

64. What are your reasons FOR participating in the study advertised above?

65. What are your reasons for NOT participating in the study advertised above?

66. How masculine or manly do you think taking part in the reproductive health trial is?

Appendix 14

Descriptions of Dimensions of the Perceived Masculinity Questionnaire (Chesebro & Fuse, 2001)

Physiological energy

Physiological energy compares androgen/testosterone levels to estrogens/progestin levels. This dimension deals with the impact of hormonal differences reflected through history and culture by asking "how desirable it is to be aggressive, assertive, competitive, dominant, or forceful in society.

Physical characteristics

Physical characteristics explore gender-related physical characteristics like being physically larger than women and having deeper voices.

Gender-related Socio-cultural roles

Gender-related Socio-cultural roles look at the social performance of masculinity as a reflection of culture. It explores what roles men are expected to perform in order to be perceived as masculine within a given culture and society.

Idealized masculinity

Idealized masculinity assesses the influence of social masculine constructions, and self- and other-perceptions of an individual's ability to be masculine.

Sexual preference

Sexual preference assesses sexual orientation, the gender and gender characteristics of one's sexual partner.

Subjective gender-identity

Subjective gender-identity measures self- and other-perceptions of the self's masculinity. This refers to how masculine one sees one's self and how one believes others see one's self.

Gender- related age identity

Gender- related age identity refers to "the social, symbolic construction of sexuality relative to one's age". For instance, prepubescent boys and elderly men are often perceived as asexual, even though it is a misnomer that elderly men are less physically able to have sex when it is usually a psychological factor.

Gender-related racial and national identities

Gender-related racial and national identities deal with the stereotypes people use to define and characterize what is and is not masculine for a particular race or national identity.

Lust

Lust is a measure of intense sexual desire, which seems to be related to masculinity. Higher levels of lusty intentions and behaviour were predicted to positively correlate with higher levels of masculinity.

Male eroticism

Male eroticism was added to "underscore the sensuous, hedonistic, suggestive, passionate, and amorous set of characteristics that have become associated with masculinity…in marketing and advertising".

<u>Interpreting Masculinity Scores on the PMQ 47 (Cheesbro & Fuse, 2002).</u>

Total Masculinity Scores for Males (n = 331)

1. Average Score: 205.3
2. Range: 151 to 249
3. Interpretation:

• Extremely High Masculinity	246 and higher
• High Masculinity	226 to 245
• Average Masculinity	186 to 225
• Low Masculinity	166 to 185
• Extremely Low Masculinity	165 and lower

Means and standard deviations of dimension scores and total score of perceived masculinity on the PMQ 47 (All U.S.A. male respondents) (Cheesbro & Fuse, 2002).

	Sample	Mean	S.D.
1. Physiological Energy	360	21.2	3.6
2. Masculine Physical Characteristics	363	18.5	2.7
4. Masculine Socio-cultural Roles	362	17.1	6.8
4. Idealized Version of Masculinity	356	22.0	3.8
5. Opposite Sex Preference	364	24.5	4.2
6. Positive Masculine Self-Conception	363	20.7	4.2
7. Positive Self-Conception of Age	361	23.8	3.4
8. Positive Self-Conception of Race	358	23.4	4.9
9. Lustful	355	13.4	3.1
10. Erotic Male Characteristics	359	20.0	3.9
TOTAL	331	205.3	20.1

Appendix 15

Ordinal regression output

SPSS ordinal regression output for dependent variable willingness to take part in the PES, factors age, continent, relationship status, number of children, and co-variable scores on the self report altruism scale, gender related socio cultural roles and physiological energy subscales of the MQ.

Model Fitting Information

Model	-2 Log Likelihood[a]	Chi-Square	df	Sig.
Intercept Only	1368.697			
Final	1317.974	50.723	13	.000

Link function: Logit.

a. The kernel of the log-likelihood function is displayed.

Parameter Estimates

		Estimate	Std. Error	Wald	df	Sig.	95% Confidence Interval	
							Lower Bound	Upper Bound
Threshold	[Study participation = 1]	2.820	.645	19.096	1	.000	1.555	4.085
	[Study participation = 2]	3.443	.652	27.919	1	.000	2.166	4.720
	[Study participation = 3]	4.295	.662	42.042	1	.000	2.996	5.593
	[Study participation = 4]	5.539	.681	66.089	1	.000	4.204	6.875
Location	Physiological Energy	.022	.020	1.166	1	.280	-.018	.062
	Socio cultural roles	.026	.011	5.049	1	.025	.003	.048
	Altruism scale	.030	.009	10.836	1	.001	.012	.047
	[Children=0]	.317	.317	1.000	1	.317	-.304	.938
	[Children=1]	.928	.398	5.448	1	.020	.149	1.707
	[Children=2+]	0[a]	.	.	0	.	.	.
	[Relationship= single]	.675	.306	4.861	1	.027	.075	1.276
	[Relationship= long term]	.290	.302	.918	1	.338	-.303	.883
	[Relationship= married or previously married]	0[a]	.	.	0	.	.	.
	[Continent=Asia & Africa]	.014	.386	.001	1	.970	-.742	.771
	[Continent=Americas]	.166	.201	.681	1	.409	-.228	.560
	[Continent=Australasia]	.676	.296	5.219	1	.022	.096	1.255
	[Continent=Europe]	0[a]	.	.	0	.	.	.
	[Age=18-27]	.601	.275	4.758	1	.029	.061	1.141
	[Age=28-37]	.268	.386	.482	1	.487	-.489	1.026
	[Age=38-47]	.493	.337	2.139	1	.144	-.168	1.154
	[Age=47+]	0[a]	.	.	0	.	.	.

Link function: Logit.

a. This parameter is set to zero because it is redundant.

Appendix 16

Spearman's Rho correlations of AQ and MQ

Correlations

			Altruism scale
Spearman's rho	Altruism scale	Correlation Coefficient	1.000
		Sig. (2-tailed)	.
		N	463
	Physiological Energy	Correlation Coefficient	.062
		Sig. (2-tailed)	.189
		N	455
	Physical Characteristics	Correlation Coefficient	.102*
		Sig. (2-tailed)	.029
		N	461
	Socio cultural roles	Correlation Coefficient	.021
		Sig. (2-tailed)	.658
		N	459
	Idealized gender	Correlation Coefficient	.131**
		Sig. (2-tailed)	.005
		N	456
	Sexual preference	Correlation Coefficient	.020
		Sig. (2-tailed)	.673
		N	456
	Subjective Gender identity	Correlation Coefficient	.232**
		Sig. (2-tailed)	.000
		N	451
	Gender related age identity	Correlation Coefficient	.086
		Sig. (2-tailed)	.068
		N	454
	Gender related national identity	Correlation Coefficient	-.066
		Sig. (2-tailed)	.163
		N	455
	Lust	Correlation Coefficient	-.238**
		Sig. (2-tailed)	.000

		N	459
	Male eroticism	Correlation Coefficient	.035
		Sig. (2-tailed)	.458
		N	454
	MQ total	Correlation Coefficient	.046
		Sig. (2-tailed)	.355
		N	407

*. Correlation is significant at the 0.05 level (2-tailed).

**. Correlation is significant at the 0.01 level (2-tailed).

Appendix 17

Interview Schedule

What were your reasons for taking part in the Pre-Cum study? What was your motivation?

What things stopped you from taking part in the study?

What was the study like? Was it what you expected?

Would you have preferred a male or female researcher to give your sample to? Would you have felt more comfortable if nobody knew your name ….. or if you could have left an unlabelled sample on a bench without seeing anyone?

Did this experience change your perception of taking part in similar studies? Would you now consider taking part in health studies / medical trials …?

Do you think it's masculine (manly) to take part in this study? Did you feel as if your masculinity was being tested? Did you have a fear of failure?

What affected your decision to take part? How do you think you're …. Influenced your decision?

- Physiological Energy
- Physical Characteristics
- Male related Socio-cultural Roles
- Gender-identity
- Gender-related Age Identity
- Gender-related Racial and National Identities
- Lust (Intense or unrestrained sexual craving)
- Male Eroticism (Sexual excitement)
- Idealized Masculinity
- Sexual Preference.

Do you think other people see taking part in the study as a masculine (manly) thing to do? How important is it that other people see you as masculine (manly)?

Do you think that it is a good thing / seen as a good thing to take part? By whom?

Do you think doing a good deed influenced your decision to take part in the study?

- Do you know anybody who has reproductive health problems? Did this influence your decision to participate?
- Do you have children / hope to have children in the future?
- Are you registered as an organ donor? Would you consider donating sperm?
- Would you require a financial incentive?

Would you discuss the results of a semen evaluation with a partner / friends / family?

How do you think men could be encouraged to take part in the study? What things would help (facilitate)? What things would prevent (be barriers)?

Appendix 18

Worked example of Interpretive Phenomenological Analysis: Creation of themes

A section of transcript from one of the participants is shown here to illustrate each stage of the IPA process. The following section is from the beginning of an interview with a male who had conducted the PES one week previously.

Extract of transcript 1

What things made you take part in that, what are your reasons for taking part?

The money. Pretty easy money really. That was pretty much the main factor I think – money. Had a bit of a laugh.

Quite enjoyable you say, a bit of a laugh?

I wouldn't say enjoyable. Maybe afterwards but more nervous to begin with. Anticipatory or whatever it is.

I guess we'll come on to the things that make you not want to take part. Were there any other reasons that made you take part?

Well it was definitely the money.

Ok, so it was all about the money. You talked briefly there about anticipatory, what made you not want to take part in the study?

Failure to perform, something like that. That would have been embarrassing.

The embarrassment, failure to perform?

Yeah

What would be embarrassing about it?

Just the fact that I knew the people that I was going with. There was more than one of us there.

Embarrassing with your peers?

Not necessarily but actually embarrassing even with someone you've never met like the woman. If I came out it was like….

What would have been embarrassing about not being able to perform?

Inadequacy.

So it would make you feel inadequate?

Yeah less of a man.

Were there any other things that made you not want to take part in this study when you think back to before you took part?

Just because I didn't know what it was like it was explained to a point what I would be doing but the procedure wasn't made clear until I got there therefore I didn't know whether it would be me with someone else like a doctor or someone or me on my own or what to do so until it was explained to me it was a degree of nervousness.

So nervousness about…

About the unknown. If I'd have known then it would have been a lot less nerve racking I think.

Were there any other things that made you nervous about the procedure that you didn't know about?

Just how the sample was going to be taken. Obviously you think of sort of sexual tests for things like STDs that doesn't make you think happy thoughts so if it was anything like that I would have been put off and probably wouldn't have actually done the tests. If it was anything to do with a swab I was going to leave.

Stage One Analysis

Transcripts were read twice to facilitate the researchers understanding of the whole text.

Stage Two Analysis

Individual transcripts were read again. The researcher noted statements of interest, commented on the use of particular language, contradictions with other parts of the transcripts, and similarities and contradictions with other participants' transcripts. Stage two was also conducted by completed by the researchers supervisor (female, 3 transcripts), a local Professor in the field of Obstetrics and Gynaecology (male, 2 transcripts), and a Trainee Clinical Psychologist (female, 5 transcripts).

Not altruistic. Money as rationalising behaviour. Conflict with later altruistic reasons. Humour. Responses brief, reflecting anxiety or embarrassment? Anticipatory anxiety. Other people's expectations of men to perform. To be able to produce sperm. Social comparisons.	**What things made you take part in that, what are your reasons for taking part?** The money. Pretty easy money really. That was pretty much the main factor I think – money. Had a bit of a laugh. **Quite enjoyable you say, a bit of a laugh?** I wouldn't say enjoyable. Maybe afterwards but more nervous to begin with. Anticipatory or whatever it is. **I guess we'll come on to the things that make you not want to take part. Were there any other reasons that made you take part?** Well it was definitely the money. **Ok, so it was all about the money. You talked briefly there about anticipatory, what made you not want to take part in the study?** Failure to perform, something like that. That would have been embarrassing. **The embarrassment, failure to perform?** Yeah **What would be embarrassing about it?** Just the fact that I knew the people that I was going with. There

Gender influences embarrassment. Masculinity connected to socio-cultural belief about ability to obtain and maintain erection and produce sample. Fear of the unknown. Exposure and reassurance. Catastrophic predictions as a barrier. Related to other stigmatised areas such as sexually transmitted diseases.	was more than one of us there. **Embarrassing with your peers?** Not necessarily but actually embarrassing even with someone you've never met like the woman. If I came out it was like…. **What would have been embarrassing about not being able to perform?** Inadequacy. **So it would make you feel inadequate?** Yeah less of a man. **Were there any other things that made you not want to take part in this study when you think back to before you took part?** Just because I didn't know what it was like it was explained to a point what I would be doing but the procedure wasn't made clear until I got there therefore I didn't know whether it would be me with someone else like a doctor or someone or me on my own or what to do so until it was explained to me it was a degree of nervousness. **So nervousness about…** About the unknown. If I'd have known then it would have been a lot less nerve racking I think. **Were there any other things that made you nervous about the procedure that you didn't know about?** Just how the sample was going to be taken. Obviously you think of sort of sexual tests for things like STDs that doesn't make you think happy thoughts so if it was anything like that I would have been put off and probably wouldn't have actually done the tests. If it was anything to do with a swab I was going to leave.

Stage Three Analysis

Emerging themes (including the researchers and colleagues interpretations) and other transcripts and links to relevant theory were documented in the right margin.

Not altruistic. Money as rationalising behaviour. Conflict with later altruistic reasons. Humour. Responses brief, reflecting anxiety or embarrassment? Anticipatory anxiety. Other people's expectations of men to perform. To be able to produce sperm. Social comparisons. Gender influences	**What things made you take part in that, what are your reasons for taking part?** The money. Pretty easy money really. That was pretty much the main factor I think – money. Had a bit of a laugh. **Quite enjoyable you say, a bit of a laugh?** I wouldn't say enjoyable. Maybe afterwards but more nervous to begin with. Anticipatory or whatever it is. **I guess we'll come on to the things that make you not want to take part. Were there any other reasons that made you take part?** Well it was definitely the money. **Ok, so it was all about the money. You talked briefly there about anticipatory, what made you not want to take part in the study?** Failure to perform, something like that. That would have been embarrassing. **The embarrassment, failure to perform?** Yeah **What would be embarrassing about it?** Just the fact that I knew the people that I was going with. There was more than one of us there.	Decision making process: pros vs. cons Performance anxiety Humour as coping. Performance anxiety. Performance anxiety; social comparisons.

embarrassment. Masculinity connected to socio-cultural belief about ability to obtain and maintain erection and produce sample. Fear of the unknown. Exposure and reassurance. Catastrophic predictions as a barrier. Related to other stigmatised	**Embarrassing with your peers?** Not necessarily but actually embarrassing even with someone you've never met like the woman. If I came out it was like…. **What would have been embarrassing about not being able to perform?** Inadequacy. **So it would make you feel inadequate?** Yeah less of a man. **Were there any other things that made you not want to take part in this study when you think back to before you took part?** Just because I didn't know what it was like it was explained to a point what I would be doing but the procedure wasn't made clear until I got there therefore I didn't know whether it would be me with someone else like a doctor or someone or me on my own or what to do so until it was explained to me it was a degree of nervousness. **So nervousness about…** About the unknown. If I'd have known then it would have been a lot less nerve racking I think. **Were there any other things that made you nervous about the procedure that you didn't know about?** Just how the sample was going to be taken. Obviously you think of sort of sexual tests for things like STDs that doesn't make you think happy	Stigma. Performance anxiety; masculinity. Performance anxiety; catastrophic predictions. Performance anxiety; exposure. Catastrophic predictions. Stigma.

areas such as sexually transmitted diseases.	thoughts so if it was anything like that I would have been put off and probably wouldn't have actually done the tests. If it was anything to do with a swab I was going to leave.	Coping; avoidance

Stage Four Analysis

Quotes from all participants' transcripts were grouped into relevant themes to enable comparisons. Emerging themes were discussed with colleagues and an expert in the field who had also analysed the transcripts and two participants. This provided a process of peer, expert and member validation for the emerging themes.

Emerging Theme	Supporting Quotes
Decision making process	"That was pretty much the main factor I think – money."
Stigma	"…but actually embarrassing even with someone you've never met like the woman" "Obviously you think of sort of sexual tests for things like STDs that doesn't make you think happy thoughts"
Fear of the unknown	"Just because I didn't know what it was like it was explained to a point what I would be doing but the procedure wasn't made clear until I got there therefore I didn't know whether it would be me with someone else like a doctor or someone or me on my own or what to do so until it was explained to me it was a degree of nervousness."

Performance anxiety; feeling less of a man Coping strategies; Humour Avoidance	**"What would have been embarrassing about not being able to perform?** Inadequacy. **So it would make you feel inadequate?** Yeah less of a man." "Had a bit of a laugh." "If it was anything to do with a swab I was going to leave."

Stage Five Analysis

Connections between themes and across transcripts were made. Super-ordinate themes were compared across transcripts and included if they were present in over half the sample.

Appendix 19

Reflective Statement

Introduction

This statement reflects upon all aspects of the research process, including the formulation of research questions, the choice of methodology, the process of conducting a systematic literature review, and the process of conducting both a quantitative and qualitative study. I aim to give a personal account of the research process, reflect upon decisions made and how completing this research project has influenced my overall understanding of research.

Formulation of a research question

The idea to undertake a research topic in the area of male reproductive health was initially proposed to me by a local Professor in the field of Obstetrics and Gynaecology. He described a paucity of males participating in a local reproductive health trial (RHT). A subsequent review of the literature revealed very little research into reasons underlying this phenomenon. The few studies I found reported that low participation rates in male RHTs were an international problem and much lower in comparison to females. I was initially interested in the psychological factors that underpin gender differences. In reflection, I had already fostered an interest in gender differences and the social construction of masculinity, being the only male in my class and entering a female dominated profession. I have also always been amazed by the capacity of people to cope with medical conditions, in particular reproductive health problems, and reflected on how I would feel in the same situation. From the outset, I assumed that research in this area was a worthwhile endeavour. Therefore, the decision to research gender differences in RHTs provided an opportunity to produce both a clinically relevant research project and research a topic of interest.

Intuition suggested that altruism is an important factor in the decision to participate in clinical trials and a literature search confirmed this (Trauth, Musa, Siminoff, Jewell, & Ricci, 2000). Unselfish displays of generosity have continually moved me and I have been fascinated by causes of altruistic behaviours from social psychology modules during undergraduate degree. I therefore decided to research the influence of masculinity and altruism on male RHT participation. In retrospect, choosing a topic of interest was a wise decision as it gave me the motivation to overcome various hurdles.

Choice of methodology

The choice of methodology posed various theoretical difficulties for me. I believe that masculinity and altruism have quite idiosyncratic meanings, thus I felt slightly awkward when attempting to quantify them. Following the peer review process with colleagues at university, I decided to use both quantitative and qualitative methodologies. Quantitative methods allowed for hypotheses about the influence of masculinity and altruism to be tested on a large sample of men. At the same time, a qualitative analysis provided a deeper understanding of individuals' experiences of RHTs and the meanings they attached to masculinity and altruism. Initially, I was concerned a mixed methodology would mean extra work and possibly affect the overall quality of each study. However, I believe that allowing participants to give qualitative comments allowed an important process of triangulation, therefore giving me more confidence to draw conclusions from results of the study. Instead of hindering my project, I think that using mixed methods allowed for a more rounded understanding of the topic.

Systematic Literature Review

Initially I (probably foolishly) thought conducting a systematic literature review would be relatively simple. However, I found myself struggling at various points throughout

the process, most notably the iterative process of implementing search strategies, refining inclusion criteria and conducting quality assurance checks. The choice of question for the review may appear quite 'dry' to other readers and at times, I too felt slightly detached from the review. On reflection, I wonder if the void of feeling towards the review reflected the state of mind of participants portrayed from the articles reviewed. As the rationale of the study suggests, most people do not consider taking part in clinical trials in day-to-day life.

I believe that the findings of the review provided a sound platform to complete both studies. The thought that each element of the thesis complement each other also provides some satisfaction. Now that I have completed one systematic review, I feel that I have both the skills and inclination to conduct systematic reviews in the future. I also feel that next time I conduct a review, the hurdles I encountered for this paper will not feel so high.

The review was written in accordance with the guidelines for authors outlined by the journal 'Trials'. I chose Trials as it publishes papers that 'encompass all aspects of the performance and findings of randomized controlled trials', has a relatively high impact factor (2.02) and 'offers a way to make data both freely available and highly visible to trialists worldwide'. Trials offered the opportunity to report findings to researchers who would benefit most from the findings without being restricted by stringent guidelines and word limits, more focused on reporting of clinical trials.

Ethics

The process of obtaining ethical approval from the Post Graduate Medical Institute seemed to be much more straightforward than reports from my peers who went through

NHS ethics boards. However, the process of obtaining ethical approval did provide a useful space to consider the methodology of the study.

Empirical study

I remember having mixed feelings about conducting a research topic in the area of male reproductive health. On the one hand, I felt a sense of pride about conducting research into a worthwhile yet seemingly unpopular area. At the same time, I recall a sense of apprehension and embarrassment about presenting proposals to study male reproductive health. In retrospect, feelings of embarrassment were partly fuelled by my perceived reactions of others and the jokes that people made. Interestingly, these experiences paralleled those of men thinking about participating in RHTs in both studies. When men were asked to think about RHTs, they were torn between feeling a 'warm glow' from helping medical science and shame associated with conducting a 'taboo act in public'. Participants often constructed RHTs as particularly stigmatised, coping with the shame of stigma with humour. I think discussing experiences of participation with participants, participating in the PES and reflecting on my own feelings helped to broaden my appreciation of male RHTs. Similar to participants, exposure to the topic helped me to feel much more relaxed talking about reproductive health. I believe that feeling more comfortable talking about sexuality and sexual difficulties has enhanced my clinical work, leading to more open discussions of patients' reproductive health where appropriate. Not having the opportunity to have more face-to-face contact with people is one of my main regrets from this experience.

Study 1

Finding a suitable way of measuring masculinity and altruism was my next significant challenge. A review of the literature suggested the Self Report Altruism Scale

(Rushden, Chrisjohn, & Fekken, 1981) has been widely used and seemed to have good reliability and validity, therefore the decision to use this scale was relatively easy. The choice of masculinity scale was much more difficult. A review of relevant literatures suggested various masculinity scales. I narrowed my choices down to the Perceived Masculinity Scale (MQ: Chesebro & Fuse, 2001) and the Gender Role Conflict Scale (GRCS: O'Neil, Helms, Gable, David, & Wrightsman, 1986). In the end, I chose the MQ due to the author's extensive research into modern constructions of masculinity and the variety of dimensions it covered.

Due to the exploratory nature of correlating dimensions of masculinity with willingness to take part in a RHT, I was quite resistant to lose dimensions of the MQ. Therefore, initial power calculations suggested that a sample size of 500 was required. At the outset, I was quite daunted yet slightly excited about the prospect of recruiting such a high number of participants. Enlisting the help of a friend who worked in internet advertising, the use of Survey Monkey and internet advertising made recruiting the 500 possible. There was inherent bias in the study due to the self-selection of participants and the style of advertisement. Nevertheless, it is likely that self-selected participants are more likely to participate in a trial and therefore representative of the target sample. Analysis of the results showed significant findings that triangulated with participants' comments and previous research. Even so, I felt that a deeper understanding of the area could have been achieved and therefore I am glad that I decided to write a qualitative paper on men's experience of clinical trials.

Study 2

I was initially quite nervous about conducting a qualitative study, as I was unsure about 'how to do it'. I had always felt comfortable with statistical analysis after completing an

A level in maths and use of statistics during my undergraduate psychology degree. However, I found the process of conducting an Interpretive Phenomenological Analysis (IPA) both enlightening and enjoyable. Carrying out an IPA study gave me an insight into the depth of meaning and understanding that the methodology allows. Whilst researching concepts such as masculinity I became acutely aware of my own social constructions and the impact these had on the study. Hence, I found the validation of themes process with both female and male colleagues both helpful and reassuring. I believe that I leant an incredible amount from completing an IPA study from start to finish and now feel much more confident about conducting qualitative research in the future. By completing an IPA study, I now have a much greater understanding of what is required for all stages of the process, such as interviews and analysis. I hope to have the opportunity to implement these skills again in the future.

Conclusion

I am satisfied that I have learnt so much from all aspects of my doctoral project. Although at times it has been challenging and frustrating, I feel that I am now equipped to go on and do further research. Reflecting on my experiences along the way has helped me to see, often frustratingly, how many of the hurdles could have been overcome in a much more efficient manner.