FULL/LONG TITLE OF THE STUDY

Image and Performance Enhancing Drugs (IPEDs): Assessment of available intelligence and research gaps to inform intervention evaluation

SHORT STUDY TITLE / ACRONYM

IPED use in the United Kingdom

PROTOCOL VERSION NUMBER AND DATE

Version 1.1 Date28/1/2021

RESEARCH REFERENCE NUMBERS

IRAS Number:	N/A
SPONSORS Number:	31474
FUNDERS Number:	NIHR 132730

[redacted]

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor: *

Signature:
.....

Date:
...../...../.....

Name (please print): Justine Daniels

Position: Director of RKE

Chief Investigator:

Signature: 

Date: 28/01/2021

Name: (please print): James McVeigh

*Agreement given awaiting signatures to be updated in Protocol Version 2.

LIST of CONTENTS

KEY STUDY CONTACTS

Chief Investigator	Prof Jim McVeigh Substance Use & Associated Behaviours Manchester Metropolitan University Geoffrey Manton Building, Rosamond Street West Manchester, M15 6LL 07503 109955/0161 147 1613 j.mcveigh@mmu.ac.uk
Study Co-ordinator	N/A
Sponsor	Manchester Metropolitan University
Joint-sponsor(s)/co-sponsor(s)	N/A
Funder(s)	NIHR
Key Protocol Contributors	N/A
Committees	N/A

STUDY SUMMARY

Study Title	Image and Performance Enhancing Drugs (IPEDs): Assessment of available intelligence and research gaps to inform intervention evaluation.
Internal ref. no. (or short title)	IPED use in the United Kingdom
Study Design	Evidence review, Delphi exercise, evidence, intervention and systems mapping and review.
Study Participants	Relevant academics
Planned Size of Sample (if applicable)	N/A
Follow up duration (if applicable)	N/A
Planned Study Period	6 months
Research Question/Aim(s)	1.Who are the relevant stakeholders? 2.What are the established networks or partnerships and how can they be enhanced? 3.Are there local/regional needs assessments to identify priorities for research? 4.What are the relevant data collected on IPED use and responses? 5.What is the underpinning research such as epidemiology? 6.Is there evidence for the adaptation of current substance use interventions or potential new approaches to address IPED use?

FUNDING AND SUPPORT IN KIND

[redacted]

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	FINANCIAL AND NON FINANCIALSUPPORT GIVEN
NIHR	£39,647.20

ROLE OF STUDY SPONSOR AND FUNDER

Details of Manchester Metropolitans role as Stundy funders to follow and be incorporated into Version 2.0 of this protocol.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Study Steering Group

Aim: To provide advice on all aspects of the project in particular in relation to:
• Progress, adherence to the protocol, and the consideration of new relevant information
• To ensure appropriate ethical and other approvals are obtained in line with the project plan
• To advise and agree protocol amendments
• To provide advice to the investigators on all aspects of the project

Membership (3)

Chair (Independent academic from external UK University), senior public policy maker, Practitioner with lived experience of IPED use.

Patient & Public Involvement Group

Public Expert Advisory Board
Involvement of those with significant understanding and experience of IPED using communities is essential to all aspects of the project

Membership
Three PEAB members contributed to the inception and proposal of the study and are joined by an additional three members to support three different functions. The team of PEAB members will:

- provide representation (at least two members) at each of the three formal project meetings
- participate in the stakeholder group workshops (WP4); and
- review outputs including final work package reports and documentation relating to any significant protocol amendments.

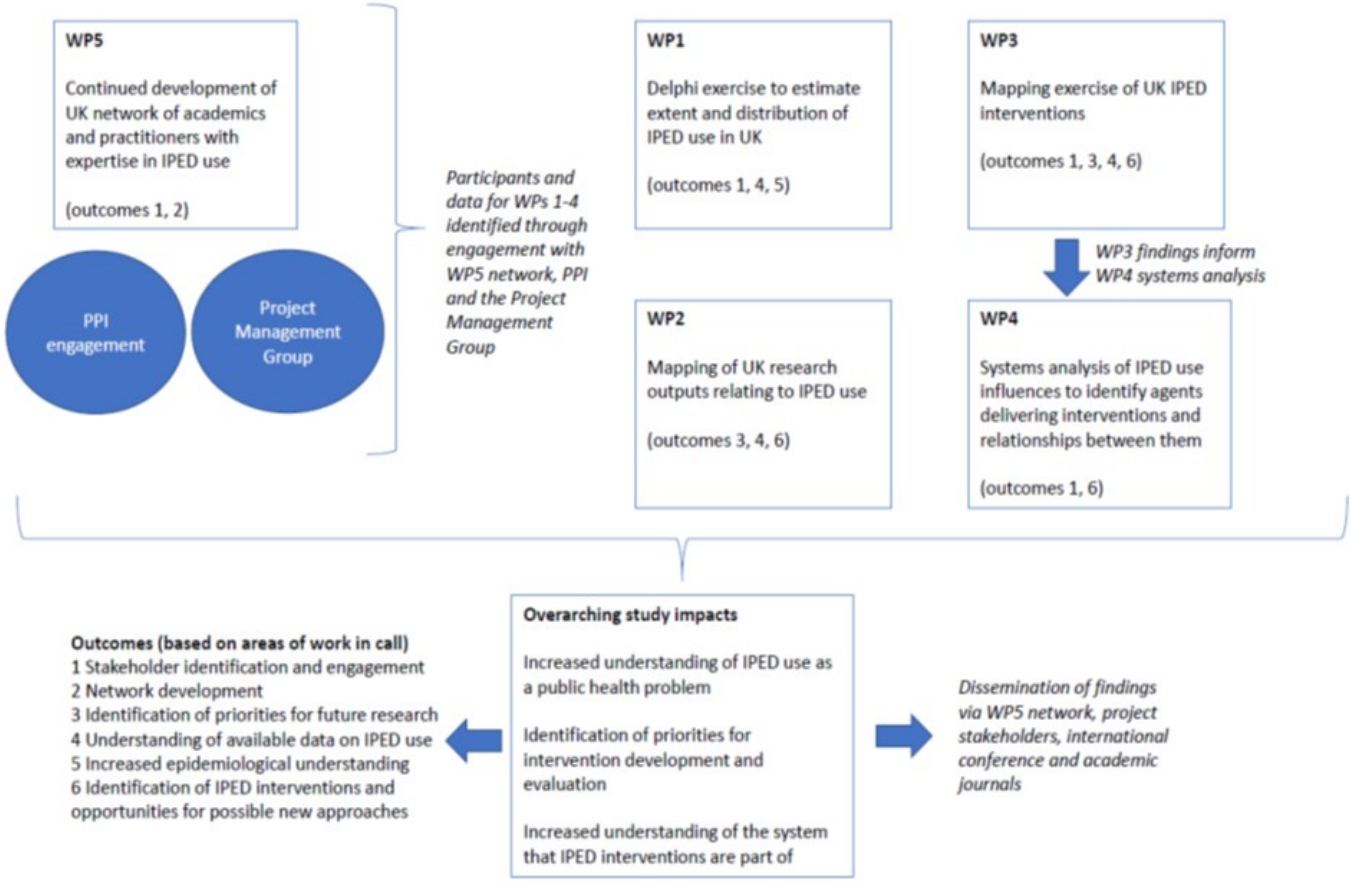
PROTOCOL CONTRIBUTORS
The protocol has been written by the Chief Investigator with input and agreement from the Co-Investigators

Chief Investigator	J McVeigh	Manchester Metropolitan University	JMcV
Co-Investigator	V Hope	Liverpool John Moores University	VH
Co-Investigator	MC Van Hout	Liverpool John Moores University	MCVH
Co-Investigator	I Boardley	University of Birmingham	IB
Co-Investigator	G Bates	University of Bath	GB
Co-Investigator	R Ralphs	Manchester Metropolitan University	RR

- The Chief Investigator with support from the co-investigators is responsible for the design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results and will be responsible for the final decision regarding any of these aspects of the study.
- The protocol has been agreed with three members of the Public Expert Advisory Board. The protocol will be reviewed by the Study Steering Group and full Public Expert Advisory Board and revised at the start up meeting to become **Protocol Version 2.0**

KEY WORDS: Image and performance enhancing drug; IPED; anabolic androgenic steroid; injection; blood borne virus, systems mapping

Figure 1 Conceptual framework of study



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STUDY PROTOCOL

Image and Performance Enhancing Drugs (IPEDs): Assessment of available intelligence and research gaps to inform intervention evaluation.

1 BACKGROUND

The use of human enhancement drugs (HEDs) to aid performance or change appearance is not a new phenomenon, with evidence of such drug use throughout recorded history(1).

Table 1: Categories of human enhancement drugs

Drug Category	Examples
Musculature	Anabolic Steroids; Human Growth Hormone
Weight Loss	Sibutramine; Clenbuterol; Dinitrophenol
Skin & Hair	Melanotan II; Mercury; Latisse
Sexual Performance	Sildenafil; Bremelanotide; Yohimbine
Cognitive Function	Methylphenidate; Modafinil; Piracetam
Mood & Behaviour	Fluoxetine; Beta-blockers; Diazepam

Note. Categories & examples of IPEDs are underlined

Table 1 illustrates six main categories of HEDs based on functionality (2) including categories that comprise IPEDs. Primarily, the term IPEDs represents drugs used to enhance physical performance and appearance (e.g., anabolic-androgenic steroids and associated drugs), but may also incorporate those used for weight loss (e.g., dinitrophenol) and altering skin colour (e.g., melanotan II). Once largely restricted to professional athletes and competitive bodybuilders, over the last thirty years IPED use has diffused to a wider population and now occurs among non-elite sports participants and recreational gym users with no involvement in organised sport(1). Whilst significant research gaps undoubtedly remain regarding IPED use, it is this group of drugs – more than any of the other HEDs – that we have evidence of harm at a population level, information relating to key populations of users and specific detail regarding their drug-use behaviours(3), as well as evidence of significant numbers contacting relevant health and support services(4, 5). For these reasons, the focus of this research specifically relates to IPED use.

Review of key evidence

The following review is predominantly based on work undertaken by McVeigh on behalf of the European Monitoring Centre for Drugs and Drug Addiction(6), but also draws upon work by Hope and colleagues(7) on risk behaviours and Bates and colleagues on systems approaches and health interventions relevant to IPED use(8-10). Where necessary, further evidence from other UK-based academics is also included. Whilst not part of the main project team, these researchers are linked to the project through their membership of Anabolic Steroids UK (ASUK) – see www.anabolicsteroids.org.uk, a network of UK IPED academics and practitioners Chaired by the Chief Investigator (JMcV) and co-ordinated through Manchester Metropolitan University.

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This research will answer the question ***What is the evidence to establish effective IPED interventions?*** We will increase the understanding of IPED use, including the nature and extent of use, current responses and the complex system that influence both behaviour and service provision. To further our understanding of IPED use, we will undertake five work packages (WPs):

WP1 Delphi exercise to estimate the extent and distribution of IPED use in the UK

WP2 Mapping of completed (published, in press, in review, in preparation, grey), ongoing & planned UK-led IPED research outputs

WP3 Mapping of current interventions targeting IPED use

WP4 Systems analysis of influences on IPED users' decision-making

WP5 Further development of the network ASUK and website www.anabolicsteroids.org.uk to:

i) support elements of data collection in this study

ii) facilitate the effective dissemination of research findings and associated outputs such as the review and mapping of current UK research literature

iii) support future research activity into IPED use in the United Kingdom

2 RATIONALE

As identified in the NIHR commissioning brief, there are a number of contributing issues that make IPED use a public health concern. It is these identified concerns that provide a rationale for the research.

1. The nature of the illicit market results in inevitable risks to the users' health. Most IPEDs are legal to possess for personal, however all supply activities (including possession with intent to supply or import through the postal system) are illegal and controlled as Class C under the Misuse of Drugs Act (1971)(7). Regardless of this, there is a wide range of oral and injectable substances readily available through direct supply (e.g., friends, training partners, gym owners, dealers or internet supply). However, legitimate products from licit pharmaceutical laboratories are rare. This creates risks of infection due to contamination and adulteration of injected materials. Further, strength of substances is rarely as purported, and substitution of active ingredients is common (7) Given many adverse effects are dose-dependent or related to specific compounds, self-management of risks is severely compromised (8).

2. Increasing prevalence and diverse populations of users is a widespread concern. Whilst IPED prevalence has not been established, the Crime Survey for England & Wales(9) and evidence from Needle and Syringe Programmes (NSPs)(4, 5) indicate an ongoing upward trend in AAS use.

3. Current IPED use is characterised by diverse populations of users with varied and often multiple motivations for use. Evidence points to diverse sub-populations of users, including older males, women and those from Black and Minority Ethnic groups(10). There are also multiple motivations for IPED use relating to appearance, strength, youthfulness, sexual performance and sports participation(11). Demographics and motivations have been combined to identify various typologies of IPED user, with contrasting risk and health profiles(12).

4. Most IPED users inject at least some of their drugs, and while blood borne viruses were not always considered a major concern amongst this population, recent studies have consistently indicated concerning levels of HIV. Also, significant levels of undiagnosed hepatitis C and low levels of hepatitis B vaccination have

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been identified, alongside widespread localised infection and soft tissue injury due to adulterated products or poor injection practices(13).

5. Polypharmacy is an established behaviour amongst people who use IPEDs, with users injecting a broad pharmacopeia of other hormones such as growth hormone and insulin, oral drugs to promote anabolism or weight loss, drugs to stimulate testosterone production and address erectile dysfunction during periods of abstinence (i.e., off- cycles). The use of peptide hormones for sunless skin tanning drugs and substances to mitigate unwanted side effects of other drugs are also common. In addition to these substances, psychoactive drug use is significantly higher than in the general population (13, 14).

6. Other risk-taking behaviours associated with IPED use are concerning. AAS use has been linked with increased risky sexual behaviour due to increasing sex drive amongst some IPED users, many of whom are already highly sexually active. Problematic alcohol use is also a risk in some sub-populations of IPED users, particularly within the context of liver toxicity linked with oral AAS(11).

7. While there remains limited evidence regarding the health impacts of long-term use of some IPEDs (e.g., human growth hormone), there have been considerable developments in identifying chronic harms linked with AAS use. These include cardiovascular disease, detrimental effects on the endocrine system and liver toxicity (i.e., oral AAS). While there remains debate regarding the role of AAS in aggression and violence, psychological harm is evident for some users and issues of AAS dependence established. Of major concern is evidence of impaired cognitive function associated with structural changes to the brain linked with prolonged high dosage AAS(15, 16).

Whilst not referred to in the NIHR call, COVID-19 has impacted on all aspects of society, including the reduction of needle and syringe collection by people who inject drugs (both psychoactive drugs and IPEDs). It remains unclear if this indicates a reduction in drug usage, other changes in drug use behaviour or the reuse or sharing of injecting equipment(17). The research will be cognisant of this, and any future implications of the pandemic.

3 THEORETICAL FRAMEWORK

To date there has been no robust evaluation of interventions to reduce the associated harms (18, 19). There are accounts of widespread uptake of public health interventions in relation to IPEDs delivered through NSPs in the UK and Australia(20), and case reports depicting the successful treatment of sequalae from IPED use(19). However, there is little evidence regarding the effectiveness of behaviour change interventions seeking to prevent or delay initiation of IPED use, reduce harm associated with use, promote cessation or prevent relapse into drug use(19).

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There is also a need to examine the wide range of factors across the socioecological spectrum that influence decision-making about IPED use, to help understand the complex relationships and dynamics involved(21). Given the proposed multiplexity of how these factors interact, a systems approach would be appropriate. Systems represent a group of interrelating and interacting components that directly or indirectly influence each other, with no part being completely independent (22). Thus, a change to one component will affect others and the combined influence of multiple components will be different from that of any individual component in isolation(23). Applying a systems perspective allows researchers, policy makers and practitioners to understand complex problems, including the components in the system and the relationships and interactions among them(24). Adopting such an approach to the study of IPED use will allow us to more fully understand the complex systems of formal and informal interventions that interact across a variety of settings and stakeholders to influence IPED use, including who the main agents are, and their priorities, perceptions and responses to the public health challenges relating to IPED use. Such research will inform our understanding of what interventions are required to address IPED use, and what their likely impact will be. This is important because incomplete understandings of systems can lead to the adoption of interventions that may seem logical but are ultimately ineffective or detrimental(25).

In contrast, a sound understanding of systems influencing IPED use will underpin research seeking to know ***"What interventions are effective and cost effective to prevent and reduce the health harms caused by the use of IPEDs?"***

The conceptual framework for this work is summarised in the attached logic model (Figure 1). The five Work Packages address the six areas of work highlighted in the call and, together, aim to enhance our understanding of IPED use as a public health issue in the UK. This will support the development and evaluation of interventions to prevent, reduce the use, or treat associated harms. To understand these interventions, we need to be able to define and specify what the problem(s) is that interventions need to address and what population(s) they need to target. By adopting a systems perspective at this stage we will identify the full range of interventions, stakeholders and populations of IPED users and make a rigorous assessment of what the most promising and important opportunities are for interventions to be developed and evaluated. It will also provide evidence critical to understanding not only the (cost) effectiveness of interventions, but their implementation and how and why they work or do not work. Key to our research approach is ***systems thinking and system maps.***

A wide range of factors across the socioecological spectrum influence decision-making about IPED use and related behaviours(21). Together these factors interact in a complex system of formal and informal interventions in a variety of settings provided by a variety of stakeholders with different perspectives, objectives and target populations. Systems represent a group of interrelating and interacting components that directly or indirectly influence each other. Importantly, no part of the system is completely independent(22) so a change to one component will have an effect on others and the combined influence of multiple components will be different from that of any individual component in isolation (23) A key implication of this is that we need to consider the interactions in and between different components in a system(26). This will support our understanding of what interventions are required in response to a problem, and what their impact is likely to be. Where we do not understand the system we are seeking to influence, this may lead to adoption of interventions that may seem logical or appropriate but are ultimately ineffective or can have negative consequences(25, 27). Applying a systems perspective supports researchers and those developing policy and practice to overcome this and to identify and understand complex problems; including the components in

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the system and, importantly, the relationships and interactions between them (24). We can develop illustrations of the important factors in a system and how they relate to and interact with another by developing system maps. Public health researchers have developed such maps when applying systems thinking to a range of problems such as physical activity(28). Developing this visual picture helps researchers and stakeholders come to a shared understanding of what the problem is (29), what the important features in the system are (for example, the key agents, processes and environments) and how the system works by illustrating the mechanisms through which these features currently or could potentially interact(30). They help to provide a wider perspective on a problem and, rather than being an end point in themselves, can be used to inform decision-making amongst a range of stakeholders(31).

System maps can have multiple impacts and benefits for researchers, policymakers and those commissioning health services and interventions. They support understanding of the factors that contribute to problems that we wish to tackle and identification of opportunity for intervention at different points in the system(31, 32); and demonstrate how multiple factors across different sectors and settings influence problems(29, 30). By understanding how systems operate it is possible to anticipate how they will react to changes (through implementation of policies or interventions) and to respond to and alleviate negative responses(33). System maps can be tailored at a local level to understand the factors contributing to a problem and opportunities to respond to this(31) and to support monitoring and evaluation of services and interventions(30). Finally, they support those delivering services and interventions to understand their roles how their work is complemented by or in conflict with other interventions and influences in the system(31).

4 RESEARCH QUESTION/AIM(S)

Beyond the overarching research question “What interventions are effective and cost effective to prevent and reduce the health harms caused by the use of IPEDs?” six research questions have been identified feeding into the study objectives.

1. Who are the relevant stakeholders?
2. What are the established networks or partnerships and how can they be enhanced?
3. Are there local/regional needs assessments to identify priorities for research?
4. What are the relevant data collected on IPED use and responses?
5. What is the underpinning research such as epidemiology?
6. Is there evidence for the adaptation of current substance use interventions or potential new approaches to address IPED use?

4.1 Objectives

- To estimate the extent and distribution of IPED use in the UK
- To map and the current IPED academic literature
- To map the current interventions targeting IPED users in the UK
- To analyse and present the major influences on IPED users’ decision-making

4.2 Outcome

To outline the available evidence and information to inform the development of an IPED intervention effectiveness evaluations

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5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

The study consists of four different data collection methods:

WP1 Delphi exercise to estimate the extent and distribution of IPED use in the UK

WP2 Mapping of completed (published, in press, in review, in preparation, grey), ongoing & planned UK-led IPED research outputs

WP3 Mapping of current interventions targeting IPED use

WP4 Systems analysis of influences on IPED users' decision-making

WP1 Referred to as ASSESS (Anabolic Androgenic Steroid Use Population Size Estimation: First Stage Study, the aim is to better understand the likely range of the size of the population using AAS and the extent that this varies geographically, so as to inform future estimation work.

In preparation for WP1, the research partners have collaborated with Public Health Wales and NHS Scotland to conduct extensive unfunded preliminary work towards estimating the prevalence of AAS use in the UK.

This unfunded work is utilising available data from Wales, Scotland and England, including publicly available data (e.g. Crime Survey), data obtained from service monitoring (NSP data were available have been accessed), obtained through data request (e.g. Crimestoppers) and research projects (held by the research team and from literature searches). These are being used to generate a range of possible estimates of the size of the AAS using population (e.g. by using multiplier approaches).

The WP will use three Delphi waves to refine the methods and assumptions used:

A. to produce local/regional estimates of the size of the AAS using population
B. for aggregating these local estimates to generate an estimate of the likely range of the national population size
C. to then refine the likely range. Waves 2 and 3 will also explore appropriate methods for use in future estimation approaches and data needs.

Drawing on the established ASUK network, experts will be invited to join the ASSESS Delphi panel. Feedback and ratings from each Delphi wave will be analysed with estimates and methods refined or discounted prior to subsequent rounds. It is anticipated that after the first round, at least two further rounds will be required to generate a likely size range of the AAS using population and to gain broad consensus on this, however there is sufficient flexibility for an additional ASSESS Delphi round to be incorporated within the time frame of this project.

WP2 will map UK-led IPED research outputs since 2015, using a scoping review methodology underpinned by the general research question ***"what do we know about UK based research on IPEDs".*** We will generate a comprehensive listing of MESH terms to guide the search (2015 to date) which will be conducted on the following databases: Web of Science; Cochrane Library; MEDLINE; PsycINFO; SPORTDiscus; Social Science Citation Index; Conf Proceedings Citation index; PubMED; Science Direct; and Researchgate. To enable the broadest picture of current knowledge and perceptions relating to recent IPED research in the UK, we will include academic and grey literature spanning policy documents and reports, online reports, conference proceedings, commentary pieces, and editorials, in addition to peer reviewed research articles.

This search will be strengthened by the inclusion of articles identified in recent literature reviews of the IPEDs evidence-base carried out by the research team(6, 18, 19, 21). Members of the ASUK Network will be provided with the draft publications list and asked for any academic and grey literature that may be missing and for any articles in press or other relevant material.

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The inclusion and exclusion criteria for the study will be discussed and agreed with all members of the research team. Duplicates and irrelevant records will be removed, included records will be charted according to features of the research such as study population, specific IPEDs, interventions and types of data collected to facilitate the identification of the breadth and depth of the evidence base and of current gaps in knowledge.

WP3 Mapping of current interventions for users (or those contemplating the use) of IPEDs.
This will include details of service provision, aims and objectives, interventions, professional skill mix, data collected, funding mechanism, permanence of service and key data elements to support NIHR effectiveness evaluation call in 2021. All relevant data are in the public domain and support for collection and collation of information will be sought from key practitioners and service managers within ASUK Network. The WP findings, in the form of a directory of interventions for people who use or who are contemplating the use of IPEDs will be made available on the ASUK website for the benefit of all stakeholders including practitioners, researchers and people who use (or may use) IPEDs.

WP4 Recruitment from ASUK will commence in February 2021 with an invitation letter and PI sheet and asked to indicate availability to participate in the two online workshops.

Two workshops will be facilitated with all participants. The dates will be confirmed based upon researcher and participant availability, but it is intended to hold them at approximately the end of March and end of April 2021.

The workshop content and delivery will be planned in February 2021. Prior to the first workshop, all participants will be given instructions on how to access and use the virtual whiteboard and invited to discuss any IT or other needs with the researchers.

The main output of this study will be a systems' map of the influences upon IPED use. The map will be developed during the workshop 1 with participants and following it by the research team. This first version will be presented at workshop 2, and further developed during and following the workshop. The second version will be disseminated to participants approximately two weeks after workshop 2, and they will be invited to send any feedback within two further weeks. Therefore, this WP will be completed by June 2021.

6 STUDY SETTING

Not applicable

7 SAMPLE AND RECRUITMENT

Recruitment is limited to pre-identified stakeholders – those academics, practitioners and other stakeholders who have joined the Anabolic Steroid United Kingdom (ASUK) Network with the intention of engaging in research and dissemination. Specific calls will be made through the network for Engagement in WP1 Delphi survey and WP4 systems mapping workshops. All academics on the ASUK Network will be asked to provide reference lists and full texts of relevant literature as defined in WP2. If there are an excess of participants available for the online workshop of WP4, selection will be made to ensure geographical representation.

7.2 Sampling

Not Applicable

7.2.1 Size of sample

Not Applicable

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[redacted]

7.2.2 Sampling technique

Not Applicable

7.3 Recruitment

Not Applicable

7.3.1 Sample identification

Not Applicable

7.3.2 Consent

- All participants engaging in WP1 and WP3 will provide informed consent.
- All potential participants will be provided the opportunity to ask questions.
- All participants will be stakeholders eg academics, policy makers, voluntary sector support staff.
- They will be considered capable of providing informed consent and participation in the study if demonstrating an understanding of the purpose and nature of the research.
- There is no risk or benefit to taking part.
- Additional participants in the WP4 Stakeholder working groups will the members of the Public Expert Advisory Board who will have attended introductory training regarding role and expectations

8 ETHICAL AND REGULATORY CONSIDERATIONS*

Work Package leads have been granted approval by their relevant ethics boards:

WP1 Delphi exercise to estimate the extent and distribution of IPED use in the UK **(LJMU)**
WP2 Mapping of UK-led IPED research outputs **(LJMU)**
WP3 Mapping of current interventions targeting IPED use **(University of Birmingham)**
WP4 Systems analysis of influences on IPED users' decision-making **(University of Bath)**

*Further approval of ethics from Manchester Metropolitan University has been submitted and will be confirmed in Protocol Version 2.0

8.1 Assessment and management of risk

Studies were considered of minimal risk and approval provided (submitted to the NIHR portal)

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

No further ethical approval is required

Regulatory Review & Compliance

Not applicable

Amendments

Due to the nature of the study and the lack of patient involvement, no amendments will impact on ethical issues or risks.

Any procedural change will be recorded by the Chief Investigator and shared with chair of study steering group. If considered of significance they will be communicated immediately to the study sponsor.

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8.3 Peer review

Due to the nature, timescale of the project this protocol has not undergone independent peer review at this stage.

8.4 Patient & Public Involvement

Public Expert Advisors (PEAs) have been involved since the inception of this call with three individuals having contributed to the thinking behind the proposal and protocol development. To date they have not received payment for their input but will be recruited to a Board with three additional members. A total of 12 days funding has been allocated between the six PEAs.

All PEAs will be provided with initial training in relation to the expectations of a PEA member and their specifically allocated role. This training will be provided at the outset of the project and will include an outline of how the project will develop, the expectations of their role, a description of individual tasks that they will be asked to perform. They will be informed of the best ways in which to communicate with the research team and how to contact the PEA manager (RR), and informed that they can withdraw at any time without notice or explanation. They will be paid for their time during this initial training and for their subsequent involvement in the project (at NIHR recognised rates). The PEA manager will remain available to members throughout the period of the research and may be contacted by PEAs if required following project completion.
In addition to ensuring that the research and interpretation of findings is sensitive to the lived experience of those using or affected by others use of IPEDs, there are three main roles of PEAs.

- To attend the 3 key meetings at the beginning, middle and near the end of the project.
- To review draft outputs and provide their privileged knowledge
- To be part of two structured focus groups re current service provision, influencing factors and other elements that will be included in the systems mapping exercise.

8.5 Protocol compliance

Any deviation from this protocol will be recorded by the Chief Investigator and reported to the sponsor. In the event of significant deviation from the protocol, the funder will be informed in writing at the earliest opportunity.

8.6 Data protection and patient confidentiality

The study is compliant with the requirements of the Data Protection Act 1998.

No patient data will be accessed or utilised. Personal data is only required for:

- WP1 contacting members of the ASUK Network for engagement in the Delphi exercise and re-contacting for subsequent contribution of views.
- WP2 – contacting and requesting literature from the academic members of the Anabolic Steroid Network (no data related to contributors will be recorded.
- WP4 – contacting members of the ASUK Network for inclusion the two workshops.
- Email addresses that have been provided to ASUK for the purpose of research will be used to contact potential participants in WP4 and contributors to WP2 and will not be linked to any participation or contributions made.
- Data access will be restricted to those within the study team with a direct need for the information.
- The information will be held securely in password protected folders with restricted access.
- Data will be destroyed after two years.
- The custodian of the data will be the Chief Investigator

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8.7 Indemnity

Full details of indemnity are available from Manchester Metropolitan University if required.

8.8 Access to the final study dataset

The research team: Chief Investigator and Co-Investigators from the four Universities will have joint access and ownership of the data

All results will be shared between Investigators, outputs will be co-written with joint authorship

- Release of findings will be subject to planned timeline, additional analyses and media engagement will be co-ordinated by the Chief Investigator and agreed by the co-investigators
- Requests for secondary data analysis will be considered by the Chief investigator and co-investigators and where possible collaboration will be encouraged

9 DISSEMINIATION POLICY

9.1 Dissemination policy

- The data will be jointly owned by the Chief Investigator and Co-Investigators
- On completion of the study, the data will be analysed and tabulated and a Final Study Report prepared for the NIHR.
- The NIHR final report will become the property of NIHR but may be hosted and accessible on each of the Investigators websites, with acknowledgment of funding from NIHR.
- All outputs will be co-authored by the Chief Investigator and the Co-investigators , additional authorship may be granted where applicable.
- All outputs will recognise the funding for the study from NIHR.
- All presentations will recognise the authorship of all Investigators and funding from NIHR.
- All reports and an Open Access peer reviewed publication will be accessible by the general public.
- Pre-formatted versions of peer reviewed publications will be available to the public through university repositories – in accordance with REF guidelines https://www.ref.ac.uk/media/1228/open_access_summary__v1_0.pdf

9.2 Authorship eligibility guidelines and any intended use of professional writers

- The final report to NIHR will be co-authored by the Chief Investigator and the Co-investigators, with additional authorship granted where applicable.
- All academic papers will be co-authored by the Chief Investigator and Co-investigators , additional authorship may be granted where applicable.

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[redacted]

10 REFERENCES

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