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A Protocol to Develop a Core Outcome Set in Incisional Hernia Surgery – The HarMoNY Project

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Manuscripts

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3 A Protocol to Develop a Core Outcome Set in Incisional Hernia Surgery – The
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5 HarMoNY Project
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10 ***NoSTRA HarMoNY***

11 (Northern Surgical Trainees Research Association Hernia & Abdominal Reconstruction - Measuring
12 Outcomes, Nociception & quality of life) collaborative research group.
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17 HarMoNY.
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30

31 Abstract

32 Introduction

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36 Incisional hernia has an incidence of up to 20% following laparotomy and is associated with significant
37 morbidity and impairment of quality of life. A variety of surgical strategies including techniques and
38 mesh types are available to manage patients with incisional hernia. Previous works have reported
39 significant heterogeneity in outcome reporting for abdominal wall herniae, including ventral and inguinal
40 hernia. This is coupled with under-reporting of important clinical and patient-reported outcomes. The
41 lack of standardisation in outcome reporting contributes to reporting bias, hinders evidence synthesis and
42 adequate data comparison between studies. This project aims to develop a core outcome set (COS) of
43 clinically important, patient-oriented outcomes to be used to guide reporting of future research in
44 incisional hernia.
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54 Methods

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58 This project has been designed as an international, multi-centre, mixed-methods project. Phase I will be
59 a systematic review of current literature to examine the current clinical and patient-reported outcomes
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3 for incisional hernia and abdominal wall reconstruction. Phase II will identify the outcomes of
4 importance to all key stakeholders through in depth qualitative interviews. Phase III will achieve
5 consensus on outcomes of most importance and for inclusion into a COS through a Delphi process. Phase
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9 IV will achieve consensus on the outcomes that should be included in a final COS.

10 11 12 13 Ethics and Dissemination

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15 Ethical approval for this study has been granted by the Health Research Authority. The results of this
16 study will be disseminated through publication in peer-reviewed journals and presentations.

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19 The adoption of this COS into clinical and academic practice will be endorsed by the American, British
20 and European Hernia Societies. Its utilisation in future clinical research will enable appropriate data
21 synthesis and comparison and will enable better clinical interpretation and application of the current
22 evidence base. This study has been registered with the Core Outcome Measures in Effectiveness Trials
23 (COMET) initiative.
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31 Trial Registration: PROSPERO registration CRD42018090084.
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34 35 Strengths and Limitations

- 36 • This project will ensure the development of an international, clinically relevant, patient-oriented
37 core outcome set to be used to guide outcome reporting in future clinical research.
- 38 • A robust systematic review will identify current outcomes in randomised and non-randomised
39 studies reporting outcomes in incisional hernia.
- 40 • In-depth qualitative interviews with key stakeholders including patients, nurses, radiologists,
41 physiotherapists, members of international hernia societies and industry partners will identify
42 outcomes of importance to all these groups.
- 43 • This project will determine which outcomes to measure, however, further work will be
44 necessary to agree and recommend a definition or measurement instrument for each of the
45 outcomes in the COS.
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58 59 60 Background

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3 Incisional hernia following laparotomy has an incidence of up to 20% and is associated with significant
4 morbidity and impairment of quality of life [1]. The management of incisional hernia has evolved over
5 recent years, with a variety of techniques, meshes and operative strategies available to manage this
6 challenging cohort of patients. Given the range of options available there is significant complexity
7 involved in the management of patients with incisional hernia. Alongside this there is considerable
8 variation in management and outcome reporting. Despite an exponential increase in the number of peer-
9 reviewed publications on the management of incisional hernia over the last decade [2], the
10 methodological quality of the majority of these studies is poor, with the majority of studies reporting
11 outcomes on incisional hernia being of Level 4 quality according to the Oxford Centre for Evidence
12 Based Medicine [3]. A recent systematic review reported over 75% of randomised controlled trials and
13 meta-analyses reporting outcomes on ventral hernias were methodologically flawed, with variable
14 adherence to standardised reporting frameworks such as Consolidated Standards of Reporting
15 Trials (CONSORT) checklist or Preferred Reporting Items for Systematic Reviews and Meta-Analyses
16 (PRISMA) Checklist PRISMA [3].

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32 There is little known about standardised outcome reporting in patients with incisional hernia. Previous
33 work examining outcome reporting for inguinal hernia identified significant variation in outcomes
34 employed to report clinical outcomes in this group. Significant heterogeneity in outcome definitions and
35 assessment instruments exist in inguinal hernia outcome reporting, alongside under-reporting of a
36 number of important clinical and patient-reported outcomes [4]. More recently, work examining outcome
37 reporting in randomised controlled trials of ventral hernia revealed marked heterogeneity in outcome
38 reporting of clinical endpoints related to hernia recurrence [5]. Subsequently, it may be hypothesised that
39 similar variation and under-reporting of relevant outcomes exists within the current literature for
40 incisional hernia repair.

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51 Core outcome sets (COS) have been developed to overcome heterogeneity in outcome reporting, reduce
52 reporting bias and enable adequate evidence synthesis, comparison of data between studies and
53 meaningful clinical interpretation and application of current evidence [6]. COS are an agreed set of
54 outcomes, which should be measured and reported, as a minimum in all studies and trials for a specific
55 clinical area. This work was initiated and developed by the COMET (Core Outcome Measures in
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3 Effectiveness Trials) initiative, which aims to facilitate and guide the development of a number of COS
4 [7]. Currently, there is no COS for incisional hernia. However, there are guidelines available to guide
5 reporting outcomes with regards to mesh properties [8] and clinical outcomes [9] associated with
6 abdominal wall repair. Although, these guidelines are useful in trying to standardise reporting outcomes,
7 they do not reflect the opinion of all stakeholders, in particular patients, when considering which
8 outcomes are of the most importance when reporting outcomes related to incisional hernia repair. To
9 improve the quality of the current evidence base and to improve outcome reporting a COS in incisional
10 hernia is highly desirable.
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20 Aims

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22 The aim of this project is to develop a COS of clinically important, patient-oriented outcomes to be used
23 to guide reporting of future research in incisional hernia.
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28 Methods

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30 An international, mixed-methods study will be conducted in accordance with Core Outcome Measures
31 in Effectiveness Trials (COMET) guidelines to develop a COS for use in incisional hernia. Phase I will
32 examine the current clinical and patient-reported outcomes for incisional hernia and abdominal wall
33 reconstruction within the literature. Phase II will identify the outcomes of importance to all key
34 stakeholders through in depth qualitative interviews. Phase III will achieve consensus on outcomes of
35 most importance and for inclusion into a COS through a Delphi process. Phase IV will achieve consensus
36 on the outcomes that should be included in a final COS.
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46 Phase I: Systematic review of clinical and patient-reported outcomes

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48 A number of detailed systematic reviews of currently reported clinical and patient reported outcomes in
49 incisional hernia and complex abdominal wall reconstruction will be conducted. The full protocol
50 including eligibility criteria and search strategy is available online via the PROSPERO database
51 (CRD42018090084).
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Phase II: Stakeholder Qualitative Interviews

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3 To ensure all key stakeholders are appropriately represented and all outcomes are captured within the
4 COS we will conduct in-depth qualitative interviews with patients and other stakeholders that are not
5 adequately represented within the current literature i.e. nurses, radiologists, physiotherapists. We will
6
7 also interview key members of the international hernia societies including the American Hernia Society,
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9 British Hernia Society and the European Hernia Society and industry partners in a bid to gauge a wider
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11 perspective.
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16 Recruitment

17 Healthcare professionals

18 All members of the American Hernia Society, the British Hernia Society and the European Hernia
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20 Society will be contacted and invited to participate.
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26 Industry Partners

27 Industry partners will be identified through key hernia organisations including the American Hernia
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29 Society, the British Hernia Society and the European Hernia Society. Industry stakeholders will be
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31 contacted and invited to participate.
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36 Patients

37 Members of the American Hernia Society, British Hernia Society and the European Hernia Society will
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39 be asked to identify potential patient participants from clinic lists, theatre lists and patient records.
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41 Recruitment letters will be sent to the identified patients, either in person during routine follow up visits
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43 or by post. The recruitment letter will give a full explanation of the qualitative interviews, instructions
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45 to participate and the contact details of the research team.
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50 Methodology

51 In-depth face-to-face or telephone cognitive interviews will be undertaken with eligible patients and
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53 stakeholders. Interviews will explore patients' perceptions and experiences regarding living with an
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55 incisional hernia and will identify the thoughts and opinions of stakeholders who are not adequately
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57 represented within the current literature. A standardised, semi-structured interview guide will inform the
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59 cognitive interviews. All interviews will be recorded. Open-ended questions will be used at the start of
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the cognitive interview followed by close-ended questions to further explore any relevant themes. To ensure appropriate representation of all stakeholders, we will conduct interviews with patients and other key stakeholders from all participating countries. We will aim to conduct between 5-10 interviews per country.

Patient Eligibility Criteria

Inclusion criteria:

- Aged >18 years old.
- With an existing incisional hernia **or**
- A surgically treated incisional hernia in the last 12 months **and**
- Able to provide written informed consent

Exclusion criteria:

- An existing other ventral hernia i.e. epigastric, umbilical, paraumbilical, inguinal, port-site hernia **or**
- A surgically treated ventral hernia i.e. epigastric, umbilical, paraumbilical, inguinal, port-site hernia **or**

To ensure our COS is representative of all stakeholders, with particular reference to patients with incisional hernia a purposive sampling strategy has been designed to aid recruitment (Table 1). Our sampling strategy will target a number of key factors to reflect the range and diversity of the target population. There is no minimal sample size for cognitive interviews.

Table 1: Purposive Sampling Strategy

Patient Factors	Number of Patients
Age	
18-30	4

31 – 60	4
>60	4
Gender	
Male	8-10
Female	8-10
Presentation	
Elective	6-8
Emergency	6-8
Repair	
Primary	6-8
Mesh	6-8
No of repairs	
1 st repair	4
Recurrent incisional hernia repair	4
Hernia size	
<10cm in width	8 – 10
>10cm in width	8 – 10
Use of adjuncts	
Yes	4
No	4
Stakeholder Factors	Number of Participants
Speciality	
General Surgery	4-6
Plastic Surgery	4-6
Radiology	4-6
Specialist nurses/physiotherapists	4-6
Industry partner	4-6
Country	
UK	4
	4

Europe	4
USA	4
Australia	

Data Analysis

All interviews will be audio recorded and transcribed verbatim and transcripts will be imported into NVivo. All transcripts will be anonymised. Interviews will be coded using the principles of thematic content analysis [10]. Relevant outcomes will be identified and appropriately coded from the transcripts using a provisional coding framework based on the outcomes extracted from the systematic review. Coded outcomes that are sufficiently similar will be grouped into similar categories and then themes. Analysis will be an iterative process, with data being analysed after rounds of three consecutive interviews. Data analysis will be continued up until the point of data saturation. This is the point on the data analysis process where no further information is elicited.

Phase III: Delphi Study

Consolidation of Outcomes

The outcomes identified in Phase I and II will be combined, developed into a long-list of items and categorised into broad domains using the principles of thematic content analysis. Appropriate questions will be mapped to these domains and will form the basis of the Delphi study. Questions will have a lay translation available. We will pilot the Delphi study with our steering committee to ensure it is accessible, comprehensible and content valid.

Forward-Backward Translation

Given the international nature of this study, we will translate the Delphi study using forward-backward translation to ensure accessibility of the study by all international participants. The aim of translation is to achieve different language versions of the original Delphi questionnaire. The linguistic and translation process should ensure that the translated version of the Delphi are conceptual, semantic and pragmatic equivalents of the original questionnaire, whilst ensuring it is culturally appropriate, relevant and

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3 meaningful to the target countries. The original Delphi questionnaire (English) will be used as the
4 standard from which all other translations are made.
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9 Forward translation will be undertaken by two healthcare professionals with an understanding of
10 incisional hernia. The translators will be bilingual with their primary language being that of the target
11 country. They will perform a detailed review of the Delphi questionnaire and translate the questionnaire
12 appropriately. Two independent translations will be prepared; these will be reviewed and compared to
13 achieve a consensus version. Any discrepancies between the translated version and the original Delphi
14 questionnaire will be discussed with the steering committee.
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22 The final translated version will be translated back into English (backward translation). This will be done
23 by a native English speaker who is also proficient in the target language. The original Delphi
24 questionnaire will be compared to the backward translation version and reviewed to ensure consistency.
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26 The aim is to ensure linguistic and conceptual equivalence between the original and translated versions
27 of the Delphi. Any discrepancies will be discussed and resolved with the steering committee and the
28 bilingual translators who undertook the forward translation. If equivalent versions have not been created
29 further translational work may be required. This may include additional forward translations and/or the
30 addition of further items/questions and will be repeated as many times as necessary to achieve a
31 satisfactory translated version.
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41 Recruitment

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45 Method of recruitment will be the same as Phase II. Healthcare professionals, patients and industry
46 stakeholders will be invited to participate through online web and social media platforms of the
47 participating hernia societies (American, British and European) and through the Northern Surgical
48 Trainees Research Association. Snowball sampling will be allowed to increase the sample size and reach
49 of the study.
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55 Sample Size

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3 There are no pre-requisite criteria for sample size for participation in Delphi studies. We hope by
4 engagement with the American, British and European hernia societies we will capture the majority of
5 individuals interested in incisional hernia.
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10 Consent

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12 No explicit consent will be obtained for participation in the Delphi study. Consent will be implied
13 through the process of participation. The registration page of the website hosting the Delphi study will
14 outline that registration to participate in the Delphi process through submission of name and email
15 address will indicate agreement to participate.
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23 Delphi Process

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25 The aim of the Delphi study is to achieve consensus amongst all key stakeholders including patients,
26 surgeons, radiologists and specialist nurses on the importance of different outcomes in sequential
27 questionnaires. The Delphi questionnaires will be developed using the DelphiManager software
28 developed by the COMET initiative. Relevant demographics will be collected for each stakeholder
29 group.
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36 Two sequential rounds of Delphi voting will be held with a feedback round in between. The first Delphi
37 round will enable participants to suggest outcomes that may not have been included or overlooked. The
38 spread of scores for each question item should reduced in between rounds as consensus is reached.
39 Following the first Delphi round participants will be provided with feedback. Participants will have
40 access to their individual scores from the first round and scores from key stakeholder group.
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48 All included outcomes will be scored on a 9 point Likert scale, with 1 being 'not essential' to 9 being
49 'absolutely essential' for inclusion into a COS. The 9 point Likert scale will be grouped into three
50 categories; 1-3 (limited importance), 4-6 (important but not critical), 7-9 (of critical importance).
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55 Consensus will be defined as the following:

56 For inclusion: more than 75% of respondents within a stakeholder group rate the outcome as critically
57 important and less than 15% of respondents rate the outcome as of limited importance.
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3 For exclusion: more than 75% of respondents within a stakeholder group the outcome as of limited
4 importance and less than 15% of respondents rate the outcome as of critical importance.
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7 No consensus
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10 11 Phase IV: Consensus Meeting 12

13 A consensus meeting of all key stakeholders will be held in conjunction with a European Hernia Society
14 meeting to discuss the results from the Delphi study. All participants registering to complete the Delphi
15 study will be invited to participate in the consensus meeting. The aim of this consensus meeting is to
16 agree on the final COS for incisional hernia. All outcomes will be discussed; a proposal will be made to
17 include all outcomes in the final COS that have been categorised as 'for inclusion' by all stakeholders
18 and to exclude all outcomes that have been categorised as 'for exclusion' by all stakeholders. Participants
19 will vote electronically to accept or reject these proposals. All other outcomes categories as 'for
20 inclusion', 'for exclusion' or 'no consensus' by one or two stakeholders will be discussed and further
21 rounds of voting will be used to agree the final COS. If no consensus is achieved a further consensus
22 meeting will be held.
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34 Patient and Public Involvement 35

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37 The HarMoNY project has been discussed with patients at national hernia meetings and has been well
38 received. A dedicated, international patient and public (PPI) steering group will be appointed to inform
39 the processes of Phases II-IV of this project. Patients will be approached by key members of the project
40 team to participate in this steering group. This PPI steering group will help inform recruitment processes,
41 help design and evaluate all patient information sheets to ensure all information is applicable and
42 understandable and advise on the content and format of dissemination of the final COS.
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51 Ethics 52

53 Ethical approval has been obtained from the Health Research Authority and Health and Care Research
54 Wales (REC 21/WA/0278). Appropriate ethical approval will be sought from all participating countries
55 in accordance with local and national guidelines. This study will be conducted in keeping with the
56 Declaration of Helsinki.
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Discussion

Defining important outcomes and standardising their reporting has been recognised to be of key importance in clinical research, which has subsequently led to the development of a number of COS. There has been a steady rise in the adoption and utilisation of COS [11], with a number of key stakeholders, including commissioners and funding bodies recognising the importance and benefits of COS for improving reporting outcomes [12]. Incisional hernia repair can be complex with significant variation in clinical management due to the great diversity of available surgical techniques [13, 14]. To ensure clinical heterogeneity is not reflected in outcome reporting the development of COS in this cohort of patients is essential. Ensuring consistent outcome reporting will reduce reporting bias, improve data synthesis and comparison, and will enable better clinical interpretation and application of the current evidence base. It is hoped through the development of a COS for incisional hernia, internationally agreed by patients, clinicians and key stakeholders, including the American, British and European Hernia Society, a minimum number of key outcomes will be reported in future clinical studies. This will help strengthen the current evidence base informing incisional hernia repair through standardised reporting.

Contributorship:

Study design: DH/CT/NS/BG/LH

Protocol writing: DH/CT/NS/BG

Methodological input: AM/FM/MM/TH/BP/AA/FK/WR

Manuscript review: MLC/LM/MM/HG/HC

Competing Interests: None

Data Sharing: None available at present

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A Protocol to Develop a Core Outcome Set in Incisional Hernia Surgery – The HarMoNY Project

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Manuscripts

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3 A Protocol to Develop a Core Outcome Set in Incisional Hernia Surgery – The
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5 HarMoNY Project
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10 ***NoSTRA HarMoNY***

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12 Outcomes, Nociception & quality of life) collaborative research group.
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30

31 Abstract

32 Introduction

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36 Incisional hernia has an incidence of up to 20% following laparotomy and is associated with significant
37 morbidity and impairment of quality of life. A variety of surgical strategies including techniques and
38 mesh types are available to manage patients with incisional hernia. Previous works have reported
39 significant heterogeneity in outcome reporting for abdominal wall herniae, including ventral and inguinal
40 hernia. This is coupled with under-reporting of important clinical and patient-reported outcomes. The
41 lack of standardisation in outcome reporting contributes to reporting bias, hinders evidence synthesis and
42 adequate data comparison between studies. This project aims to develop a core outcome set (COS) of
43 clinically important, patient-oriented outcomes to be used to guide reporting of future research in
44 incisional hernia.
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54 Methods

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58 This project has been designed as an international, multi-centre, mixed-methods project. Phase I will be
59 a systematic review of current literature to examine the current clinical and patient-reported outcomes
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3 for incisional hernia and abdominal wall reconstruction. Phase II will identify the outcomes of
4 importance to all key stakeholders through in depth qualitative interviews. Phase III will achieve
5 consensus on outcomes of most importance and for inclusion into a COS through a Delphi process. Phase
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9 IV will achieve consensus on the outcomes that should be included in a final COS.

10 11 12 13 Ethics and Dissemination

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15 The adoption of this COS into clinical and academic practice will be endorsed by the American, British
16 and European Hernia Societies. Its utilisation in future clinical research will enable appropriate data
17 synthesis and comparison and will enable better clinical interpretation and application of the current
18 evidence base. This study has been registered with the Core Outcome Measures in Effectiveness Trials
19 (COMET) initiative.
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26 Trial Registration: PROSPERO registration CRD42018090084.
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29 30 Strengths and Limitations

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32 • This project will ensure the development of an international, clinically relevant, patient-oriented
33 core outcome set to be used to guide outcome reporting in future clinical research.
- 34
35 • A robust systematic review will identify current outcomes in randomised and non-randomised
36 studies reporting outcomes in incisional hernia.
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38 • In-depth qualitative interviews with key stakeholders including patients, nurses, radiologists,
39 physiotherapists, members of international hernia societies and industry partners will identify
40 outcomes of importance to all these groups.
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42 • This project will determine which outcomes to measure, however, further work will be
43 necessary to agree and recommend a definition or measurement instrument for each of the
44 outcomes in the COS.
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53 54 Background

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56 Incisional hernia following laparotomy has an incidence of up to 20% and is associated with significant
57 morbidity and impairment of quality of life [1]. The management of incisional hernia has evolved over
58 recent years, with a variety of techniques, meshes and operative strategies available to manage this
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3 challenging cohort of patients. Given the range of options available there is significant complexity
4 involved in the management of patients with incisional hernia. Alongside this there is considerable
5 variation in management and outcome reporting. Despite an exponential increase in the number of peer-
6 reviewed publications on the management of incisional hernia over the last decade [2], the
7 methodological quality of the majority of these studies is poor, with the majority of studies reporting
8 outcomes on incisional hernia being of Level 4 quality according to the Oxford Centre for Evidence
9 Based Medicine [3]. A recent systematic review reported over 75% of randomised controlled trials and
10 meta-analyses reporting outcomes on ventral hernias were methodologically flawed, with variable
11 adherence to standardised reporting frameworks such as Consolidated Standards of Reporting
12 Trials (CONSORT) checklist or Preferred Reporting Items for Systematic Reviews and Meta-Analyses
13 (PRISMA) Checklist PRISMA [3].

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26 There is little known about standardised outcome reporting in patients with incisional hernia. Previous
27 work examining outcome reporting for inguinal hernia identified significant variation in outcomes
28 employed to report clinical outcomes in this group. Significant heterogeneity in outcome definitions and
29 assessment instruments exist in inguinal hernia outcome reporting, alongside under-reporting of a
30 number of important clinical and patient-reported outcomes [4]. More recently, work examining outcome
31 reporting in randomised controlled trials of ventral hernia revealed marked heterogeneity in outcome
32 reporting of clinical endpoints related to hernia recurrence [5]. Subsequently, it may be hypothesised that
33 similar variation and under-reporting of relevant outcomes exists within the current literature for
34 incisional hernia repair.

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45 Core outcome sets (COS) have been developed to overcome heterogeneity in outcome reporting, reduce
46 reporting bias and enable adequate evidence synthesis, comparison of data between studies and
47 meaningful clinical interpretation and application of current evidence [6]. COS are an agreed set of
48 outcomes, which should be measured and reported, as a minimum in all studies and trials for a specific
49 clinical area. This work was initiated and developed by the COMET (Core Outcome Measures in
50 Effectiveness Trials) initiative, which aims to facilitate and guide the development of a number of COS
51 [7]. Currently, there is no COS for incisional hernia. However, there are guidelines available to guide
52 reporting outcomes with regards to mesh properties [8] and clinical outcomes [9] associated with
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3 abdominal wall repair. Although, these guidelines are useful in trying to standardise reporting outcomes,
4 they do not reflect the opinion of all stakeholders, in particular patients, when considering which
5 outcomes are of the most importance when reporting outcomes related to incisional hernia repair. To
6 improve the quality of the current evidence base and to improve outcome reporting a COS in incisional
7 hernia is highly desirable.
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14 Aims

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16 The aim of this project is to develop a COS of clinically important, patient-oriented outcomes to be used
17 to guide reporting of future research in incisional hernia.
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23 Methods

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25 An international, mixed-methods study will be conducted in accordance with Core Outcome Measures
26 in Effectiveness Trials (COMET) guidelines to develop a COS for use in incisional hernia. Phase I will
27 examine the current clinical and patient-reported outcomes for incisional hernia and abdominal wall
28 reconstruction within the literature. Phase II will identify the outcomes of importance to all key
29 stakeholders through in depth qualitative interviews. Phase III will achieve consensus on outcomes of
30 most importance and for inclusion into a COS through a Delphi process. Phase IV will achieve consensus
31 on the outcomes that should be included in a final COS.
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41 Phase I: Systematic review of clinical and patient-reported outcomes

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43 A number of detailed systematic reviews of currently reported clinical and patient reported outcomes in
44 incisional hernia and complex abdominal wall reconstruction will be conducted. The full protocol
45 including eligibility criteria and search strategy is available online via the PROSPERO database
46 (CRD42018090084).
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54 Phase II: Stakeholder Qualitative Interviews

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56 To ensure all key stakeholders are appropriately represented and all outcomes are captured within the
57 COS we will conduct in-depth qualitative interviews with patients and other stakeholders that are not
58 adequately represented within the current literature i.e. nurses, radiologists, physiotherapists. We will
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3 also interview key members of the international hernia societies including the American Hernia Society,
4 British Hernia Society and the European Hernia Society and industry partners in a bid to gauge a wider
5 perspective.
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10 Recruitment

11 Healthcare professionals

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13 All members of the American Hernia Society, the British Hernia Society and the European Hernia
14 Society will be contacted and invited to participate.
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20 Industry Partners

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22 Industry partners will be identified through key hernia organisations including the American Hernia
23 Society, the British Hernia Society and the European Hernia Society. Industry stakeholders will be
24 contacted and invited to participate.
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30 Patients

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32 Members of the American Hernia Society, British Hernia Society and the European Hernia Society will
33 be asked to identify potential patient participants from clinic lists, theatre lists and patient records.
34 Recruitment letters will be sent to the identified patients, either in person during routine follow up visits
35 or by post. The recruitment letter will give a full explanation of the qualitative interviews, instructions
36 to participate and the contact details of the research team.
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44 Methodology

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46 In-depth face-to-face or telephone cognitive interviews will be undertaken with eligible patients and
47 stakeholders. Interviews will explore patients' perceptions and experiences regarding living with an
48 incisional hernia and will identify the thoughts and opinions of stakeholders who are not adequately
49 represented within the current literature. A standardised, semi-structured interview guide will inform the
50 cognitive interviews. All interviews will be recorded. Open-ended questions will be used at the start of
51 the cognitive interview followed by close-ended questions to further explore any relevant themes. To
52 ensure appropriate representation of all stakeholders, we will conduct interviews with patients and other
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key stakeholders from all participating countries. We will aim to conduct between 5-10 interviews per country.

Patient Eligibility Criteria

Inclusion criteria:

- Aged >18 years old.
- With an existing incisional hernia **or**
- A surgically treated incisional hernia in the last 12 months **and**
- Able to provide written informed consent

Exclusion criteria:

- An existing other ventral hernia i.e. epigastric, umbilical, paraumbilical, inguinal, port-site hernia **or**
- A surgically treated ventral hernia i.e. epigastric, umbilical, paraumbilical, inguinal, port-site hernia **or**

To ensure our COS is representative of all stakeholders, with particular reference to patients with incisional hernia a purposive sampling strategy has been designed to aid recruitment (Table 1). Our sampling strategy will target a number of key factors to reflect the range and diversity of the target population. There is no minimal sample size for cognitive interviews.

Table 1: Purposive Sampling Strategy

Patient Factors	Number of Patients
Age	
18-30	4
31 – 60	4
>60	4

Gender	
Male	8-10
Female	8-10
Presentation	
Elective	6-8
Emergency	6-8
Repair	
Primary	6-8
Mesh	6-8
No of repairs	
1 st repair	4
Recurrent incisional hernia repair	4
Hernia size	
<10cm in width	8 – 10
>10cm in width	8 – 10
Use of adjuncts	
Yes	4
No	4
Stakeholder Factors	Number of Participants
Speciality	
General Surgery	4-6
Plastic Surgery	4-6
Radiology	4-6
Specialist nurses/physiotherapists	4-6
Industry partner	4-6
Country	
UK	4
Europe	4
USA	4
Australia	4

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Data Analysis

All interviews will be audio recorded and transcribed verbatim and transcripts will be imported into NVivo. All transcripts will be anonymised. Interviews will be coded using the principles of thematic content analysis [10]. Relevant outcomes will be identified and appropriately coded from the transcripts using a provisional coding framework based on the outcomes extracted from the systematic review. Coded outcomes that are sufficiently similar will be grouped into similar categories and then themes. Analysis will be an iterative process, with data being analysed after rounds of three consecutive interviews. Data analysis will be continued up until the point of data saturation. This is the point on the data analysis process where no further information is elicited.

Phase III: Delphi Study

Consolidation of Outcomes

The outcomes identified in Phase I and II will be combined, developed into a long-list of items and categorised into broad domains using the principles of thematic content analysis. Appropriate questions will be mapped to these domains and will form the basis of the Delphi study. Questions will have a lay translation available. We will pilot the Delphi study with our steering committee to ensure it is accessible, comprehensible and content valid.

Forward-Backward Translation

Given the international nature of this study, we will translate the Delphi study using forward-backward translation to ensure accessibility of the study by all international participants. The aim of translation is to achieve different language versions of the original Delphi questionnaire. The linguistic and translation process should ensure that the translated version of the Delphi are conceptual, semantic and pragmatic equivalents of the original questionnaire, whilst ensuring it is culturally appropriate, relevant and meaningful to the target countries. The original Delphi questionnaire (English) will be used as the standard from which all other translations are made.

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5 Forward translation will be undertaken by two healthcare professionals with an understanding of
6 incisional hernia. The translators will be bilingual with their primary language being that of the target
7 country. They will perform a detailed review of the Delphi questionnaire and translate the questionnaire
8 appropriately. Two independent translations will be prepared; these will be reviewed and compared to
9 achieve a consensus version. Any discrepancies between the translated version and the original Delphi
10 questionnaire will be discussed with the steering committee.
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18 The final translated version will be translated back into English (backward translation). This will be done
19 by a native English speaker who is also proficient in the target language. The original Delphi
20 questionnaire will be compared to the backward translation version and reviewed to ensure consistency.
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22 The aim is to ensure linguistic and conceptual equivalence between the original and translated versions
23 of the Delphi. Any discrepancies will be discussed and resolved with the steering committee and the
24 bilingual translators who undertook the forward translation. If equivalent versions have not been created
25 further translational work may be required. This may include additional forward translations and/or the
26 addition of further items/questions and will be repeated as many times as necessary to achieve a
27 satisfactory translated version.
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36 37 38 Recruitment

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41 Method of recruitment will be the same as Phase II. Healthcare professionals, patients and industry
42 stakeholders will be invited to participate through online web and social media platforms of the
43 participating hernia societies (American, British and European) and through the Northern Surgical
44 Trainees Research Association. Snowball sampling will be allowed to increase the sample size and reach
45 of the study.
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52 53 Sample Size

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55 There are no pre-requisite criteria for sample size for participation in Delphi studies. We hope by
56 engagement with the American, British and European hernia societies we will capture the majority of
57 individuals interested in incisional hernia.
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Consent

No explicit consent will be obtained for participation in the Delphi study. Consent will be implied through the process of participation. The registration page of the website hosting the Delphi study will outline that registration to participate in the Delphi process through submission of name and email address will indicate agreement to participate.

Delphi Process

The aim of the Delphi study is to achieve consensus amongst all key stakeholders including patients, surgeons, radiologists and specialist nurses on the importance of different outcomes in sequential questionnaires. The Delphi questionnaires will be developed using the DelphiManager software developed by the COMET initiative. Relevant demographics will be collected for each stakeholder group.

Two sequential rounds of Delphi voting will be held with a feedback round in between. The first Delphi round will enable participants to suggest outcomes that may not have been included or overlooked. The spread of scores for each question item should be reduced in between rounds as consensus is reached. Following the first Delphi round participants will be provided with feedback. Participants will have access to their individual scores from the first round and scores from key stakeholder group.

All included outcomes will be scored on a 9 point Likert scale, with 1 being 'not essential' to 9 being 'absolutely essential' for inclusion into a COS. The 9 point Likert scale will be grouped into three categories; 1-3 (limited importance), 4-6 (important but not critical), 7-9 (of critical importance).

Consensus will be defined as the following:

For inclusion: more than 75% of respondents within a stakeholder group rate the outcome as critically important and less than 15% of respondents rate the outcome as of limited importance.

For exclusion: more than 75% of respondents within a stakeholder group rate the outcome as of limited importance and less than 15% of respondents rate the outcome as of critical importance.

No consensus

Phase IV: Consensus Meeting

A consensus meeting of all key stakeholders will be held in conjunction with a European Hernia Society meeting to discuss the results from the Delphi study. All participants registering to complete the Delphi study will be invited to participate in the consensus meeting. The aim of this consensus meeting is to agree on the final COS for incisional hernia. All outcomes will be discussed; a proposal will be made to include all outcomes in the final COS that have been categorised as 'for inclusion' by all stakeholders and to exclude all outcomes that have been categorised as 'for exclusion' by all stakeholders. Participants will vote electronically to accept or reject these proposals. All other outcomes categories as 'for inclusion', 'for exclusion' or 'no consensus' by one or two stakeholders will be discussed and further rounds of voting will be used to agree the final COS. If no consensus is achieved a further consensus meeting will be held.

Patient and Public Involvement

The HarMoNY project has been discussed with patients at national hernia meetings and has been well received. A dedicated, international patient and public (PPI) steering group will be appointed to inform the processes of Phases II-IV of this project. Patients will be approached by key members of the project team to participate in this steering group. This PPI steering group will help inform recruitment processes, help design and evaluate all patient information sheets to ensure all information is applicable and understandable and advise on the content and format of dissemination of the final COS.

Ethics

Ethical approval has been obtained from the Health Research Authority and Health and Care Research Wales (REC 21/WA/0278). Appropriate ethical approval will be sought from all participating countries in accordance with local and national guidelines. This study will be conducted in keeping with the Declaration of Helsinki.

Discussion

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3 Defining important outcomes and standardising their reporting has been recognised to be of key
4 importance in clinical research, which has subsequently led to the development of a number of COS.
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6 There has been a steady rise in the adoption and utilisation of COS [11], with a number of key
7 stakeholders, including commissioners and funding bodies recognising the importance and benefits of
8 COS for improving reporting outcomes [12]. Incisional hernia repair can be complex with significant
9 variation in clinical management due to the great diversity of available surgical techniques [13, 14]. To
10 ensure clinical heterogeneity is not reflected in outcome reporting the development of COS in this cohort
11 of patients is essential. Ensuring consistent outcome reporting will reduce reporting bias, improve data
12 synthesis and comparison, and will enable better clinical interpretation and application of the current
13 evidence base. It is hoped through the development of a COS for incisional hernia, internationally agreed
14 by patients, clinicians and key stakeholders, including the American, British and European Hernia
15 Society, a minimum number of key outcomes will be reported in future clinical studies. This will help
16 strengthen the current evidence base informing incisional hernia repair through standardised reporting.
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30 **Contributorship:**

31 Study design: DH/CT/NS/BG/LH

32 Protocol writing: DH/CT/NS/BG

33 Methodological input: AM/FM/MM/TH/BP/AA/FK/WR

34 Manuscript review: MLC/LM/MM/HG/HC

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41 **Competing Interests:** None

42 **Data Sharing:** None available at present

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