

Appendix A: Review screening process

Initial Literature review question:

What is known about therapeutic engagement in secure settings?

Definitions:

Secure settings: Prison, secure hospital, or other institution where the individual is detained and has committed a crime or crimes which have resulted in their admission/incarceration.

Therapeutic engagement: The process of being involved in planned interpersonal therapeutic work. NB. Not relating to general personal or professional engagement; nor relating specifically to the psychotherapeutic concept of “therapeutic alliance”.

Men: Aged 18 or over.

Literature search criteria:

All search result numbers exclude non-peer reviewed articles, and excluding duplicates; all searches applied related words. All search terms were in unspecified domains (title, abstract, keywords) unless otherwise specified.

Searches:

The document highlights 4 searches, with respective details on why, how and what resulted. Although a number of searches were completed before and between each of the 4 searches outlined here, these recorded highlight a change in search term and/or criteria that were considered necessary to build on the previously accepted search strategy (of which these were the 4 accepted strategies at different stages).

Screening process guide, used in all searches:

Stage A: Filtering lists of search results initially by title using the following key:

1 = Yes (from the information in the title, this has potential to meet the inclusion criteria, and evades the exclusion criteria).

2 = Maybe (it is unclear if it meets the inclusion criteria, or if it meets exclusion criteria). It requires further investigation (of abstract).

3 = No (it is clear that it either does not meet the inclusion criteria, and/or meets exclusion criteria).

Stage B: Following completion of stage A, the abstract of each number 1 and 2 was screened to give a further code:

1 = Yes (from the information in the abstract, this has potential to meet the inclusion criteria, and evades the exclusion criteria).

2 = Maybe (it is unclear if it meets the inclusion criteria, or if it meets exclusion criteria). It requires further investigation (of full paper).

3 = No (it is clear that it either does not meet the inclusion criteria, and/or meets exclusion criteria).

Stage C: Following completion of Stage B, all papers designated 1 or 2 were read in entirety to give a final code:

1 = Yes the paper meets the inclusion criteria, and evades the exclusion criteria.

3 = No, the paper does not meet the inclusion criteria, and/or meets exclusion criteria.

Appendix B: Preliminary review searches

Search 1

Purpose:	The initial search was to determine the factors relevant in the research question.
Terms:	(engag* AND therap*) and (forensic OR prison* OR jail OR inmate* OR secure.
Search Results:	548
Process:	Screening stage A, conducted by PI and research supervisor (97% overlap in 1 and 2s). Screening stage B and C conducted by PI.
Inclusion:	<p>A) Relating to secure care.</p> <p>B) Relating to interpersonal (individual or group) therapy, not medical or other physical treatment.</p> <p>C) Subject of (or substantial contribution of) paper is regarding the nature, exploration or definition of therapeutic engagement; and/or in how it is measured, or improved.</p>
Exclusion:	<p>1) Not as above.</p> <p>2) ("Therapy") related to offending, as opposed to clinical/healthcare matters, including drug treatments.</p> <p>3) Relating to intellectual disability services.</p>
Results:	5 papers met inclusion criteria.
Comments:	<p>After more detailed consideration, it was understood that the inclusion criteria needed to be redesigned as there was an element of contradiction. There were a number of papers which related to substance use, however they did not involve medical treatment (unknown to the PI and research supervisor until greater investigation), and therefore these papers were excluded at all stages of the screening in search 1.</p> <p>Furthermore, there were papers related to therapies associated with offending behaviours, which had been excluded. Upon more detailed consideration of the range of literature in the field, it was decided to remove this exclusion criteria.</p>

Search 2

Purpose:	Because the focus of the study was on therapeutic engagement with men, the search question was amended to reflect this (and to reduce the number of results for greater reliability): "What is known about therapeutic engagement in secure settings for men?" The new search would also reflect the updated inclusion and exclusion criteria.
Terms:	(engag* AND therap*) AND (forensic OR prison* OR jail OR inmate* OR secure) AND (men or male)
Search results:	103 (117 before duplicates removed)
Process:	Screening stage A, conducted by PI and research supervisor (96% overlap in 1s and 2s) Screening stage B and C conducted by PI.
Inclusion:	A) Relates to secure care. B) Relating to interpersonal (individual or group) therapy C) Subject of (or substantial contribution of) paper is regarding the nature, exploration or definition of therapeutic engagement; and/or in how it is measured, or improved.
Exclusion:	1) Not as above. 2) Medical or other physical treatment (including substance misuse, drug treatment and HIV). 3) Relating to intellectual disability services.
Results:	7 papers (including 4 from search 1 [not 126])
Comments:	Following the analysis of the papers it became apparent that many therapeutic interventions in secure care were packaged as programmes, despite containing predominantly therapeutic aspects. This led to a final re-design of inclusion/exclusion criteria.

Search 3

Purpose:	Search 2 provided the same results as search 1, with two additional papers which had previously been excluded on the basis of their focus on substance use or violent offending. The PI was aware of a paper which had not been selected using the
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search terms, which met the inclusion criteria (and did not meet the exclusion criteria). It was found that by selecting men or male in the “all text” option gave access to this paper in the results, as well as a further three.

- Terms: (engag* AND therap*) AND (forensic OR prison* OR jail OR inmate* OR secure) AND (men or male [ALL TEXT])
- Search results: 186
- Process: Screening stage A, B, and C conducted by PI. Due to the overlap with searches 1 and 2, the papers had predominantly already been through screening stage A by the research supervisor.
- Inclusion criteria: Relating to secure settings; relating to individual/group therapy or therapeutic programmes; and subject of (or substantial contribution of) paper is regarding the nature, exploration, or definition of TE, and/or in how it is measured, or improved.
- Exclusion criteria: Not as per inclusion criteria; and treatment programmes using medical or physical means, or drugs/medication. Relating to intellectual disability services.
- Results: 11 papers (including all 7 from Search 2 and all 5 from Search 1)**

Search 4

- Purpose: Due to the PI finding a further paper which met criteria, however was not selected using search terms, the keyword specified on that paper “therapeutic relationships” was added for search 4 which included that paper plus two others.
- Terms: ((engag* AND therap*) OR “therapeutic relationships”) AND (forensic OR prison* OR jail OR inmate* OR secure) AND (men or male [ALL TEXT])
- Search results: 219 [271 before removing duplicates) On 5th December 2013
=121 Psychinfo, 95 Academic search complete, 55 cinhal plus with full text
(Web of knowledge = 219 [before duplicates = no difference)
- Process: Screening stage A, B, and C conducted by PI. Due to the overlap with searches 1 and 2, the papers had predominantly

already been through screening stage A by the research supervisor.

Inclusion and exclusion: As per Search 3

Results: **10 papers (including all 12 from Search 3)**

10 Papers were: 8, 9, 30, 34, 53, 62, 72, 104, 161, 162.

CONTINUING SEARCH:

Since December 5th 2013 an E-mail auto response from EBSCO sent all new papers which meet the search terms (search 4) to the PI. Each paper was evaluated using screening stages A, B and C. To this date (22nd April 2014), no additional papers have qualified for further critical review.

Appendix C: Qualitative paper screening tool

- 1) **What were the aims?**
What were the research questions? Were these clearly stated? Was the significance and relevance clearly stated?
- 2) **Was the choice of qualitative methodology appropriate?**
Was the design used appropriate for the aims? Did the authors justify their choice of method (compared to others)? Could it have been investigated better using a different design? Was the design appropriate for general/specific aims? Was the design congruous with methodological guidelines? Were any interventions used described sufficiently?
- 3) **Was bias considered?**
Did the authors state their theoretical orientations / personal anticipations (owning one's perspective)? Were these considered in the formulation of the method? Were there any conflicts of interest?
- 4) **Were ethical issues considered?**
Was there sufficient information to determine if ethical procedures were followed (in design, consent, and recruitment)? Did the authors consider outcomes on participants and other stakeholders during and following the study? Was the relationship between researcher and participants considered? Was there service user involvement in the design, analysis and dissemination?
- 5) **Was the recruitment of participants appropriate?**
Was the recruitment strategy appropriate? Was the sample situated with sufficient information? Were the participants appropriate to give access to the data required? Were all those approached accounted for?
- 6) **Was data collection conducted in an appropriate way?**
Were the data collection methods and settings described clearly and explicitly? Was justification given for the method? Was the form of data used clear and justified? Was saturation of data discussed?
- 7) **Was the data analysed with sufficient rigor?**
Was the data analysis described in sufficient detail for replication? Was the data analysis credible (e.g. triangulation, followed recommended guidelines)? Did the researchers critically examine their own roles in analysis and dissemination? For interpretative methods, was there evidence that the original data had been interpreted?
- 8) **Was there a clear statement of findings?**
Did these relate to the aims? Were they discussed in relation to the original research question? Were the themes coherent and integrated? Were there arguments for and against?
- 9) **Was the presentation of data appropriate?**
Were extracts of data used to provide examples of themes? Did the extracts presented provide evidence for the suggested themes? Could the themes be understood from the data/extracts

presented? Was contradictory data considered? Was the analysis process made clear by offering an explanation of how the presented data was selected? Have they considered null results?

10) What were the **clinical implications**?

Has transferability been discussed? Were further study/follow ups suggested?

11) Had the study been considered in the context of **existing literature**?

Did the author(s) critically evaluate the literature relating to the subject? Did they consider positions that they do not agree with? How did the results sit with existing literature?

12) Did the publication **resonate** with the reader?

Did it accurately represent the subject matter or further understanding of the subject? Were experiences brought to life?

Appendix D: Quantitative paper screening tool

- 1) Was the research addressing a **clearly focussed** issue?
Were the aims and research question(s) clear and relevant? Was the population well defined? Were the outcomes considered?
- 1) Was the choice of quantitative **methodology** appropriate?
Did the authors justify their choice of method (compared to others)? Was the design used appropriate for the aims? Was the method described in sufficient detail? Could it have been investigated better using a different design? Was the design appropriate for general/specific aims? Were any interventions used described sufficiently?
- 2) Were all **variables clearly defined**?
For example: Outcome, exposure, predictor, potential confounder, & effect modifier variables.
- 3) Was **bias** considered?
Were measurements objective? Were there any conflicts of interest (for participants/researchers)? Were potential sources of bias addressed?
- 4) Were **ethical issues** considered?
Was there sufficient information to determine if ethical procedures were followed (in design, consent, and recruitment)? Did the authors consider outcomes on participants and other stakeholders during and following the study? Was there service user involvement in the design, analysis and dissemination?
- 5) Was the **recruitment** of participants appropriate?
Was the recruitment strategy (including sampling and inclusion/exclusion criteria) appropriate? Were the participants representative of a defined population? Was group assignment randomised? Was everyone included who should have been included? Were the participants suitably described? Were all those approached accounted for at the end?
- 6) Was **data collection** conducted in an appropriate way?
Were the data collection methods (including researchers) and settings described clearly and explicitly? Were the assessment tools used validated? Were assessments used consistently across groups?
- 7) Was the data analysed with sufficient **rigor**?
Was the data analysis described in sufficient detail for replication? Was the data analysed in a way that addressed the study aims? Did the researchers critically examine their own roles in analysis and dissemination?
- 8) Was there a clear statement of **results**?
What were the results? Did these relate to the aims? Were they discussed in relation to the original research question? Were there arguments for and against?
- 9) Was the **presentation of results** appropriate?
Were effect sizes, probabilities and statistics clearly and accurately reported? Do these justify the conclusions? Was contradictory data considered? Were all important outcomes considered? Have they

considered null results? Were potential limitations (e.g. bias, imprecision) discussed? Were all participants accounted for at analysis/follow up?

10) What were the **clinical implications**?

Could the findings be applied? Was generalisability discussed? Were further study/follow ups suggested? Were follow ups reported? Were any potential harms considered?

11) Had the study been considered in the context of **existing literature**?

Did the author(s) critically evaluate the literature relating to the subject? Did they consider positions that they do not agree with? How did the results sit with existing literature? What does it add to our knowledge?

Appendix E: Certificate of indemnity



26th July 2012

VERIFICATION OF INSURANCE**TO WHOM IT MAY CONCERN**

We act as insurance brokers to the above client and in this capacity can provide brief details of their current Professional Indemnity policy

Insured	Keele University, Keele University Science Park Ltd and Keele University Science and Business Park Ltd.
Insurer	RSA Group
Period of Insurance	1 st August 2012 to 31 st July 2013
Policy Number	SA13328793
Limit of Indemnity	<p>£5,000,000 for each claim and in the aggregate in respect of all claims first made in any one period of insurance with one automatic reinstatement of the limit to provide an additional £5,000,000 of cover in the aggregate if the first £5,000,000 is exhausted.</p> <p>In respect of claims made against the Insured in the USA or Canada the Limit of Indemnity is restricted to £1,000,000 in the aggregate in any one period of insurance, with no automatic reinstatement.</p>
Excess	£25,000 each and every claim

This document is provided for information only and is subject to Insurers policy terms, conditions, limitations and exclusions. Cover may also be subject to cancellation provisions and warranties.

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 Authorised and regulated by the Financial Services Authority and a Lloyd's broker
 A list of the designated members and individual members of Lockton Companies LLP is available for inspection at the registered office

Appendix F: Peer review approval



RESEARCH AND ENTERPRISE SERVICES

2 October 2012

Kieran Lord
Staffordshire & Keele Universities Doctorate in Clinical Psychology
R207 Faculty of Sciences
Staffordshire University
Leek Road
Stoke on Trent
ST4 2DF

Dear Kieran

Service Users' view of clinical psychologists' engagement in secure care

As you know the above project was initially awarded a grade 2 but following receipt of your response to the issues raised the project has now received final approval from the Independent Peer Review Committee and proceed for submission to an NHS REC for ethical approval. Please find attached the peer review comments for the above project.

Management approval

You should arrange for all relevant NHS care organisations to be notified that the research will be taking place, and provide a copy of the REC application, the protocol and this letter.

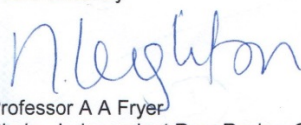
All researchers and research collaborators who will be participating in the research must obtain management approval from the relevant care organisation before commencing any research procedures. Where a substantive contract is not held with the care organisation, it may be necessary for an honorary contract to be issued before approval for the research can be given.

Clinical trial of a medicinal product

Please remember that, if your project is a clinical trial of a medicinal product, MHRA approval is required. You must submit a request for a clinical trial authorisation under the Medicines for Human Use (Clinical Trials) Regulations 2004. Further details can be found at <http://www.mhra.gov.uk/home/groups/l-unit1/documents/websiteresources/con2022633.pdf>

If you have any queries, please do not hesitate to contact Nicola Leighton on 01782 733306.

Yours sincerely

pp 

Professor A A Fryer
Chair – Independent Peer Review Committee

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RESEARCH AND ENTERPRISE SERVICES

2 October 2012

Chair
NHS Research Ethics Committee

Dear Sir/Madam

Investigator : Kieran Lord
Name of study :

Please find attached the peer review of the above project.

Although the peer reviewer awarded a grade 1 the project was initially awarded a grade 2 by the Peer Review Committee as members agreed that Kieran should address the following two minor points before approval could be given:-

- Consideration of the wording of the questions to ensure that these are not misleading
- Clarification as to whether the final themes will be validated with the participants before writing up.

The Independent Peer Review Committee are satisfied that the issues raised have been answered and that the project can now be awarded a grade 1 and therefore can proceed for ethical review without any revision.

We have informed the applicant that although this project has been deemed appropriate based on scientific merit, they wish to incorporate the reviewer's constructive comments to strengthen their protocol.

We have also stressed to the applicant that the Independent Peer Review Committee is NOT linked to or a Sub-Committee of the Local Research Ethics Committee and that you may identify ethical issues of your own.

If you have any queries, please do not hesitate to contact Nicola Leighton on 01782 733306.

Yours sincerely

pp

Professor AA Fryer
Chair – Independent Peer Review Committee

Enc



**Keele
University**

RESEARCH AND ENTERPRISE SERVICES

PEER REVIEWER'S PROFORMA

Research Project Details	
Project title	Service Users' views of clinical psychologists' engagement in secure care
Name of principal investigator	Kieran Lord
Institution of principal investigator	Student : Staffordshire/Keele Universities Doctorate in Clinical Psychology
The important or relevance of the problem to be addressed in relation to either or both of:	
<p>a) The particular field of research as a whole</p> <p>This is an important piece of research and could have a significant impact on the field.</p>	
<p>b) The value of this research for health or social care</p> <p>The rationale for this study was stated clearly. Its findings will be very useful in practice.</p>	
The quality and relevance of the background information provided	
Background literature was very well-researched. Systematic reviews, policy and strategic documents have also been cited.	
Design, methods and strengths and weakness of the proposed plan of investigation	
<p>The research method and design proposed are suitable to address the research questions. Semi-structured interviews will allow the researcher to explore in-depth the service users' perspectives; however, these may also be subject to social desirability. The researcher, therefore, needs to be careful with the wording of the questions so that these are not leading. They also need to re-assure the participants that they will not be judged for their responses and that these will be kept confidential and anonymous to encourage openness and honesty.</p>	



**Keele
University**

RESEARCH AND ENTERPRISE SERVICES

The quality of analysis provided (statistical or qualitative, as appropriate)

The analysis has been detailed well. However, the researcher needs to clarify whether the final themes will be validated with the participants before writing-up.

The capacity and expertise of the research team in the context of the proposed study

Very good. I am confident that the research team should be able to manage this research well.

Appropriateness of resource requirements

Fine.

General feedback (indicate major areas where changes will be required, indicate whether any weaknesses indicated in any of the above categories are major-or minor areas of concern)

This is an excellent and well-thought proposal. I have no major concerns and am happy for this project to be submitted for NHS ethics approval.

Assessment of Merit

Grade	Description	Please tick
1	Proceed without any revision. Project may be submitted for appropriate NHS/University approval and then to either the Local or the Multi-Centre Research Ethics Committee.	x
2	Minor amendments or Further information required. Revise project according to reviewer(s) recommendations. Document to be checked by Internal Committee Member prior to Chairman's approval to proceed.	
3	Complete major revision required. Principal Investigator to discuss outcome with Centre/Programme Director and agree plan to complete substantive revision of the project (with support as agreed). Resubmission will need to be reviewed and approved by Internal Committee Member, prior to Chairman's approval to proceed.	
4	Reject on the basis that the project has major scientific flaws	

Appendix G: NHS proportionate review unfavourable opinion

T:\ETHICS\CORRESPONDENCE\2013 correspondence\K Lord SL8(PR)16-1-13.docx
 Part of the research infrastructure for Wales funded by the National Institute for Social Care and Health Research, Welsh Government.
 Yn rhan o seilwaith ymchwil Cymru a ariannir gan y Sefydliad Cenedlaethol ar gyfer Ymchwil Gofal Cymdeithasol ac Iechyd, Llywodraeth Cymru

NISCHR

Gwasanaeth
Moeseg
Ymchwil

RES

Research
Ethics
Service

16 January 2012

South West Wales Research Ethics Committee
 Floor 8
 36 Orchard Street
 Swansea
 SA1 5AQ

Telephone : 01792 607416
 Fax : 01792 607533
 E-mail : penny.beresford@wales.nhs.uk
 Website : www.nres.nhs.uk

Mr Keiran Lord
 Trainee Clinical Psychologist
 North Staffordshire Combined NHS
 Staffordshire & Keele Universities Doctorate in Clinical Psychology
 Staffordshire University Science Centre
 Leek Road, Stoke-On-Trent
 ST4 2DF

Dear Mr Lord

Study title: Qualitative investigation into service users' views about engagement by clinical psychologists working in forensic settings using interpretative phenomenological analysis
REC reference: 13/WA/0023
Protocol number: n/a

The Proportionate Review Sub-Committee of the Research Ethics Committee reviewed the above application on 16 January 2013.

Ethical issues

The Committee felt that this application had material ethical issues and that a review at a full REC meeting is required in order to give an opinion on the study.

- The Committee had some concerns regarding the recruitment procedure and patient welfare. The questionnaire is not yet prepared so the committee had no idea of the questions to be asked and how patients would react if certain immediate reactions occurred as to how they would be handled on the spot or what measures would be taken should a patient become distressed.

There were also concerns regarding the 'ex forensic service user research group' to guide the questioning.

- The committee felt that the information sheet could be clearer in what information the researchers will be collecting from the care record, not just age and gender, and the language made a little easier to understand.
- The committee felt that the potential high sensitivity of the encounter had not been fully addressed and did not therefore fulfil the NMEIT type V.



GIG
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Bwrdd Iechyd
Addysgu Powys
Powys Teaching
Health Board

Cynhelir Cydweithrediad Gwyddor Iechyd Academaidd y Sefydliad Cenedlaethol ar gyfer Ymchwil Gofal Cymdeithasol ac Iechyd gan Fwrdd Addysgu Iechyd Powys

The National Institute for Social Care and Health Research Academic Health Science
 Collaboration is hosted by Powys Teaching Health Board



Ariennir gan
Llywodraeth Cymru
Funded by
Welsh Government

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Arrangements for further review

We have referred your application back to the local allocation service for review by a full REC.

The REC now appointed to review your application is:

North Wales REC (Central & East), G1/G2 Croesnewydd Hall, Croesnewydd Road, Wrexham Technology Park, LL13 7YP. Tel 01978 726377.

The co-ordinator from the above REC, Mrs Tracy Biggs, will write to you with further details of the meeting at which your application is to be reviewed. We will send on copies of all paperwork relating to this application to the above REC on your behalf.

The 60 day clock for giving an ethical opinion on the application has not stopped at this point. An ethical opinion on the application will be given within 60 days of receipt of a valid application by this Committee. The clock has been adjusted to take account of your choice of the above REC rather than the first available REC meeting offered to you.

Membership of the Proportionate Review Sub-Committee

The members of the sub-committee who took part in the review are listed on the attached sheet.

Documents reviewed

The documents reviewed were:

Document	Version	Date
Evidence of insurance or indemnity		26 July 2012
Investigator CV		06 January 2013
Other : CV for Helena Priest		01 January 2007
Participant Consent Form	1.1	05 July 2012
Participant Information Sheet	1.1	05 July 2012
Protocol	1	05 July 2012
REC application	1	07 January 2013

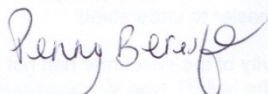
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

13/WA/0023

Please quote this number on all correspondence

Yours sincerely



Roy L Evans
Chairman

Appendix H: NHS REC unfavourable opinion

Part of the research infrastructure for Wales funded by the National Institute for Social Care and Health Research, Welsh Government.
Yn rhan o seilwaith ymchwil Cymru a ariannir gan y Sefydliad Cenedlaethol ar gyfer Ymchwil Gofal Cymdeithasol ac Iechyd, Llywodraeth Cymru



North Wales REC (Central & East)
G1/G2 Croesnewydd Hall
Croesnewydd Road
Wrexham Technology Park
Wrexham LL13 7YP

Telephone : 01978 726377

E-mail : tracy.biggs@wales.nhs.uk

Website : www.nres.nhs.uk

08 February 2013

Mr Kieran M Lord
Trainee Clinical Psychologist
North Staffordshire Combined NHS
Staffordshire and Keele Universities Doctorate in Clinical Psychology
Staffordshire University Science Centre
Leek Road, Stoke-On-Trent
ST4 2DF

Dear Mr Lord

Study title: Qualitative investigation into service users' views about engagement by clinical psychologists working in forensic settings using interpretative phenomenological analysis.
REC reference: 13/WA/0023
IRAS project ID: 108003

The Research Ethics Committee reviewed the above application at the meeting held on 06 February 2013. Thank you for attending to discuss the study.

Ethical opinion

The members of the Committee present decided that it was unable to give a favourable ethical opinion of the research, for the following reasons:

Members were in full agreement with the original reviewing committee's comments:

- The Committee had some concerns regarding the recruitment procedure and patient welfare. The questionnaire is not yet prepared so the committee had no idea of the questions to be asked and how patients would react if certain immediate reactions occur as to how they would be handled on the spot or what measures would be taken should a patient become distressed.
- The Committee felt that the information should be clearer in what information the researchers will be collecting from the care record, not just age and gender, and the language made a little easier to understand.

However, an additional concern was that there was no guarantee that prisoners or offenders supervised by the probation service could be excluded from participation as there was no adequate mechanism in place for screening out of the research process.

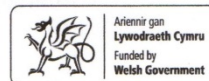
You agreed that there was no guarantee or clear strategy confirmation and welcomed the suggestion to resubmit to an appropriately flagged REC to cover potential offender or probationer participation.

Coordinator contact details were provided to you to facilitate the resubmission.



Cynhelir Cydweithrediad Gwyddor Iechyd Academaidd y Sefydliad Cenedlaethol ar gyfer Ymchwil Gofal Cymdeithasol ac Iechyd gan Fwrdd Addysgu Iechyd Powys

The National Institute for Social Care and Health Research Academic Health Science Collaboration is hosted by Powys Teaching Health Board



The Committee agreed that as the research involves a vulnerable population there ought to be adequate support mechanisms for both the participant and researcher.

The Committee noted Northern Ireland had been selected at filter question however there was no indication of any sites in Northern Ireland being involved. Clarification was provided by you that there is no intention to have a site located in Northern Ireland however, filter question 3 is not allowing de-selection.

Clarification was provided by you that an ex-forensic service user research group within Manchester University will be consulted in the drafting of the formatted questions before resubmission.

The Committee recommends that you consider the following before a resubmission:

- 1) Please provide a clear recruitment process.
- 2) Ensure there are adequate support/welfare mechanisms in place for participants and researcher.
- 3) a) Participant Information Sheet to include details of welfare or distress policy/mechanisms.
b) Information should be added to the beginning of the sheet to explain that the study is being undertaken as part of an educational qualification.
- 4) Please ensure the summary of study is completed in lay language in readiness for publication. Guidance can be found at A6-1 of the REC form.
- 5) Please provide the formatted questions (interview schedule) following consultation with the ex-service user researcher group panel.
- 6) Further consideration in the selection of answers to filter question 8, if applicable, and A6-3 of the REC application form.

I regret to inform you therefore that the application is not approved.

If you would find it helpful to discuss any of the matters raised above or seek further clarification from a member of the Committee, you are welcome to contact the Coordinator at the REC office in the first instance.

Options for further ethical review

You may submit a new application for ethical review, taking into account the Committee's concerns. You should enter details of this application on the application form and include a copy of this letter, together with a covering letter explaining what changes have been made from the previous application. We strongly recommend that you submit the new application to this REC. However, you may submit the application to a different REC if you prefer.

Alternatively, you may appeal against the decision of the Committee by seeking a second opinion on this application from another Research Ethics Committee. The appeal would be based on the application form and supporting documentation reviewed by this Committee, without amendment. If you wish to appeal, you should notify the relevant Research Ethics Service manager (see below) in writing within 90 days of the date of this letter. If the appeal is allowed, another REC will be appointed to give a second opinion within 60 days and the second REC will be provided with a copy of the application, together with this letter and other relevant correspondence on the application. You will be notified of the arrangements for the meeting of the second REC and will be able to attend and/or make written representations if you wish to do so.

The contact point for appeals is:

Joan Kirkbride
Director of Operations
National Research Ethics Service

Email: joan.kirkbride@nhs.net

Documents reviewed

The documents reviewed at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Evidence of insurance or indemnity		26 July 2012
Interview Schedules/Topic Guides	1	18 January 2013
Investigator CV		06 January 2013
Other: CV - Helena Priest		01 January 2007
Other: Application for peer review		05 July 2012
Participant Consent Form	1.1	05 July 2012
Participant Information Sheet	1.1	05 July 2012
Protocol	1	18 January 2013
REC application		07 January 2013

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

Here you will find links to the following:

- a) Providing feedback. You are invited to give your view of the service you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website
- b) Re-submission/Appeal.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

13/WA/0023

Please quote this number on all correspondence

Yours sincerely

T.A. Briggs.

PP

Professor Alex Carson
Chair

Enclosures:

List of names and professions of members who were present at the meeting and those who submitted written comments.

Copy to:

Nicola Leighton, Keele University
Professor Eleanor Bradley, South Staffordshire and Shropshire Healthcare
NHS Foundation Trust

North Wales REC (Central and East)

Attendance at Committee meeting on 06 February 2013

Committee Members:

Name	Profession	Present	Notes
Mrs Celia Blomeley	Retired Assistant Headteacher	Yes	
Professor Alex Carson Chair	Associate Dean (Research)	Yes	
Dr Kath Clarke	Deputy Associate Chief of Staff, Nursing	Yes	
Dr John Clifford	Consultant Psychiatrist	Yes	
Reverend Kathy Collins	Chaplain /Lay Member	Yes	
Dr John Delieu	Anatomist & DI for HTA Licence	Yes	
Mr John Gittins	Coroner	Yes	
Miss Joy Hickman	Consultant Orthodontist	Yes	
Dr Peter Hobson	Principal Healthcare Scientist (Research)	No	
Ms Alison Ledward	Former Midwife/Current Researcher	Yes	
Mrs Lucy Lewis	Paediatric Research Nurse	No	
Mr Philip Richards	Associate Specialist - Surgery	Yes	
Mrs Elaine Roberts	Antimicrobial Pharmacist	No	
Dr David Southern	Consultant Anaesthetist	Yes	
Ms Eunice Vincent	Retired Nurse/Nurse Lecturer	Yes	
Dr Anthony White	Consultant Care of the Elderly	Yes	
Dr Diane Williamson	Consultant Dermatologist	Yes	

Also in attendance:

Name	Position (or reason for attending)
Mrs Tracy Biggs	Research Ethics Committee Co-ordinator
Dr Corinne Scott	Research Ethics Operational Manager

Appendix I: NHS REC favourable opinion

Part of the research infrastructure for Wales funded by the National Institute for Social Care and Health Research, Welsh Government.
Yn rhan o seilwaith ymchwil Cymru a ariannir gan y Sefydliad Cenedlaethol ar gyfer Ymchwil Gofal Cymdeithasol ac Iechyd, Llywodraeth Cymru



NISCHR

Gwasanaeth
Moeseg
Ymchwil

RES

Research
Ethics
Service

North Wales REC (Central & East)
G1/G2 Croesnewydd Hall
Croesnewydd Road
Wrexham Technology Park
Wrexham LL13 7YP

Telephone : 01978 726377

E-mail : tracy.biggs@wales.nhs.uk

Website : www.nres.nhs.uk

02 May 2013

Mr Kieran M Lord
Trainee Clinical Psychologist
North Staffordshire Combined NHS
Staffordshire and Keele Universities Doctorate in Clinical Psychology
Staffordshire University Science Centre
Leek Road, Stoke-On-Trent
ST4 2DF

Dear Mr Lord

Study title: Qualitative investigation into service users' views about engagement by clinical psychologists working in forensic settings using interpretative phenomenological analysis.

REC reference: 13/WA/0122

IRAS project ID: 130185

The Research Ethics Committee reviewed the above application at the meeting held on 01 May 2013. Thank you for attending to discuss the application.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Mrs Tracy Biggs, Tracy.Biggs@wales.nhs.uk.

Ethical opinion

The Committee agreed that the revised protocol provided a clearer recruitment and consent process and the resubmission overall was greatly improved.

The Committee queried whether the interview schedule was likely to be modified. Confirmation was provided that this was the final version. However, one answer may provide the answer to later questions but no additional questions would be added.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

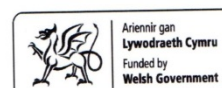
NHS Sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).



Cynhelir Cydweithrediad Gwyddor Iechyd Academaidd y Sefydliad Cenedlaethol ar gyfer Ymchwil Gofal Cymdeithasol ac Iechyd gan Fwrdd Addysgu Iechyd Powys

The National Institute for Social Care and Health Research Academic Health Science Collaboration is hosted by Powys Teaching Health Board



Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

- Participant documentation should be proof read to amend any typographical or grammatical errors, such as within the section: What will it involve for me? '... and what things you feel what not work'.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Covering Letter		10 April 2013
Interview Schedules/Topic Guides	2	10 April 2013
Investigator CV	K Lord	06 January 2013
Investigator CV	H Priest	10 January 2013
Other: Copy unfavourable opinion letter		08 February 2013
Participant Consent Form	2	10 April 2013
Participant Information Sheet	2	10 April 2013
Protocol	2	10 April 2013
REC application	0	10 April 2013

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

13/WA/0122

Please quote this number on all correspondence

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

With the Committee's best wishes for the success of this project.

Yours sincerely

T.A. Biggs

PP

Professor Alex Carson
Chair

E-mail: tracy.biggs@wales.nhs.uk

Enclosures:

List of names and professions of members who were present at the meeting and those who submitted written comments
"After ethical review – guidance for researchers"

Copy to:

Nicola Leighton, Keele University
Professor Eleanor Bradley, South Staffordshire and Shropshire Healthcare
NHS Foundation Trust

North Wales REC (Central and East)

Attendance at Committee meeting on 01 May 2013

Committee Members:

Name	Profession	Present	Notes
Mrs Celia Blomeley	Retired Assistant Headteacher	No	
Professor Alex Carson Chair	Associate Dean (Research)	Yes	
Dr Kath Clarke	Deputy Associate Chief of Staff, Nursing	Yes	
Dr John Clifford	Consultant Psychiatrist	Yes	
Reverend Kathy Collins	Chaplain /Lay Member	Yes	
Dr John Delieu	Anatomist & DI for HTA Licence	No	
Mr John Gittins	Acting Coroner	No	
Miss Joy Hickman	Consultant Orthodontist	Yes	
Dr Peter Hobson	Principal Healthcare Scientist (Research)	Yes	
Ms Alison Ledward	Former Midwife/Current Researcher	Yes	
Mrs Lucy Lewis	Paediatric Research Nurse	No	
Mr Philip Richards	Associate Specialist - Surgery	No	
Mrs Elaine Roberts	Antimicrobial Pharmacist	No	
Dr David Southern	Consultant Anaesthetist	Yes	
Ms Eunice Vincent	Retired Nurse/Nurse Lecturer	No	
Dr Anthony White	Consultant Care of the Elderly	Yes	

Also in attendance:

Name	Position (or reason for attending)
Mrs Tracy Biggs	Research Ethics Committee Co-ordinator

Appendix J: Local trust research and development approval

South Staffordshire and Shropshire Healthcare **NHS**

NHS Foundation Trust

Our Ref: AB/R243

4 June 2013

Mr Kieran Lord
 Trainee Clinical Psychologist
 Staffordshire and Keele Universities
 R207, Faculty of Sciences
 Leek Road
 Stoke on Trent ST4 2DF

Research and Development
 Block 7
 St George's Hospital
 Corporation Street
 STAFFORD
 ST16 3AG
 Tel: (01785) 221168
 Email: audrey.bright@ssstf.nhs.uk

Dear Kieran

Study title: Service user views of clinical psychologist engagement in secure care

We have considered your application for access to patients and staff from within this Trust in connection with the above study.

On behalf of the Trust the Lead Officer for Research Governance (Eleanor Bradley), and the Responsible Care Professionals within the Psychology Directorate have now satisfied themselves that the requirements for Research Governance, both Nationally and Locally, have been met and are happy to give approval for this study to take place in the Trust, with the following provisos:

- That all researchers coming into the Trust have been issued with either a letter of access or honorary contract by ourselves
- That you conform to the requirements laid out in the letters from the REC dated 3 May 2013, which prohibits any changes to the agreed protocol
- That you keep the Trust informed about the progress of the project at 6 monthly intervals
- If at any time details relating to the research project or researcher change, the R&D department must be informed.

Your research has been entered into the Trust database and will appear on the Trust website.

As part of the Research Governance framework it is important that the Trust are notified as to the outcome of your research and as such we will request feedback once the research has finished along with details of dissemination of your findings. You will be asked to provide a copy of the final report and receive an invitation to present final feedback via our research seminar series. To aid dissemination of findings, copies of final reports are placed on our Trust Website. To this end, please contact me towards the completion of the project to discuss the dissemination of findings across the Trust and a possible implementation plan.


If I can help in any other way please do not hesitate to contact me.

Yours sincerely



Professor Eleanor Bradley
 Head of Research and Development
 Cc Dr Felix Davies, Director of Psychological Services, Trust HQ, Stafford

Appendix K: Consent form

Version 3: 2nd May 2013South Staffordshire and Shropshire Healthcare 
NHS Foundation Trust

Patient Identification code for this trial:

Consent Form**Service Users' Perceptions of Engagement by Clinical Psychologists**

Please initial each box:

1. I confirm that I have read and understand the information sheet dated 2nd May 2013. (version 3) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

☐

3. I understand that an audio recording will be made of the interview which will be transcribed and sections may be used in the presentation of findings. I understand that only the research team will have access the recording/transcription and that any identifiable information will be removed.

☐

4. I understand that the research team will record age and gender information from my medical notes. I understand that the purpose of this is to show the overall characteristics of the participants in the study.

☐

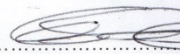
5. I agree to my responsible clinician being informed of my participation in the study.

☐

6. I agree to take part in the above study.

☐

Name of service user.....Date.....Signature.....

Name of person taking consent. HERAN CORD.....Date.....Signature.....

Position of person taking consent. CLINICAL PSYCHOLOGIST IN TRAINING.....
(When completed: 1 copy for participant; 1 for researcher site file.)

Appendix L: Participant information sheet

Version 3: 2nd May 2013

South Staffordshire and Shropshire Healthcare 
NHS Foundation Trust

Participant Information Sheet

Service Users' Perceptions of Engagement by Clinical Psychologists

You have been invited to take part in a research study about engagement. In this study engagement refers to the motivations of, and methods used by clinical psychologists and service users, when establishing therapeutic relationships. This study is being undertaken as part of a Doctorate of Clinical Psychology qualification at Staffordshire and Keele Universities by Kieran Lord. Please read through the following information before you decide to be involved. You will be given at least 24 hours to decide. Please contact the research team or your care team if you have any questions.

What is this research study about?

The study aims to speak to service users who have experiences of care in secure settings. We would like to better understand what people in this position feel about how clinical psychologists may have engaged with them, and how they would like to be engaged. We feel it is important to understand these experiences from the service user's perspective so that we can approach care in a way that is sensitive to service users' needs.

Who will be taking part?

People who are currently in secure care and have views or experience of engagement by clinical psychologists. The study will require between three and twelve participants.

What will it involve for those who choose to take part?

You are under no obligation to take part in this study; your involvement is entirely voluntary.

If you choose to take part you will be invited to talk about your experiences with, and views about, engagement by clinical psychologists. The questions will give you an opportunity to talk about how you may have experienced being approached by, or being engaged in treatment with clinical psychologists. These may be positive or negative views. They will also give you an opportunity to speak about how you think clinical psychologists might best approach engagement and what things you feel would not work. You do not have to talk about anything that you are uncomfortable talking about. This will last around 60 minutes and will be audio recorded. The interview will take place in a private room at your location. We will also take a record of your age and gender. This is to help us get an idea of the characteristics of the people who take part in the study.

All the information that you provide will be kept confidential and only seen by members of the study team. The only time that this confidentiality would be breached is if it became apparent that there had been a disclosure of harm or potential harm to self or others, or criminal activity. The audio recordings will be locked securely and only be available to the research team, they will be destroyed once the conversations have been transcribed and the research has been completed. Your name will not be used in any findings which may be published so you will not be identifiable; some quotes taken from the tapes may be used but will have any identifying information removed. We will be informing your responsible clinician if you choose to be involved in the study but will not be giving them any details of what you may say.



KEELE
UNIVERSITY



STAFFORDSHIRE
UNIVERSITY

Version 3: 2nd May 2013

South Staffordshire and Shropshire Healthcare 
NHS Foundation Trust

What are the advantages and disadvantages of taking part?

We hope that by investigating the views of service users in secure care that this will add to our knowledge about how clinical psychologists can best approach their work in future to ensure service users get the best care.

If we feel your involvement in the research will cause you unnecessary distress we will not ask you to participate further. We recognise that you may however become distressed by talking about experiences that you have had to the research team. We will give you the opportunity to talk about anything that may have distressed you with a separate member of your care team, including a clinical psychologist. You will have 24 hour access to your care team who will be informed of your involvement. We will ask you before your involvement who the best person (or people) would be for you to seek support from in the event of you feeling distressed. You do not have to answer any individual questions and can withdraw from the study without giving a reason at any time.

Do you have to take part?

No, it is your choice if you would like to take part. You will be given at least 24 hours to consider if you want to, and then will be then asked to complete a consent form. We are very grateful to you for considering this information whether you choose to take part or not.

Can you withdraw from the study if you change your mind?

Yes, you can choose to stop your involvement in the study at any stage and do not need to inform us why. Once we have begun analysis of the information from the interviews we cannot withdraw that information, however it will be anonymous. Any decision you make regarding the study will not affect your care.

What should you do if you decide to take part?

If you chose to take part then after at least 24 hours you will be asked to complete a consent form to say you have read this information sheet and that you are happy to take part.

Who is conducting the research?

The interviews will be conducted by **Kieran Lord** (Trainee Clinical Psychologist), and will be supervised by **Dr Amanda McGowan** (Clinical Psychologist). Both are experienced at working in secure settings and conducting this type of research. The study is in part being used to complete the research requirement of Kieran's doctoral training programme.

What if there is a problem?

If you have any concerns please contact Kieran Lord or Amanda McGowan on **01782 294 007**. If you remain unhappy and wish to complain formally, you can do this by contacting Audrey Bright, Research Governance, South Staffordshire and Shropshire Healthcare NHS Foundation Trust, Research Office, Block 7, St George's Hospital, Corporation St, Stafford, ST16 3AG. Or call 01785 221 409 or email on: Audrey.Bright@sssft.nhs.uk.

Further information

If you would like any further information please contact Kieran Lord on **01782 294 007**. For further information from someone who is independent of this research you could contact the Patient Advice and Liaison Service (PALS – www.pals.nhs.uk) on **0800 587 4793**, or **01785 221469**.

Who has reviewed this study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed by the North Wales Research Ethics Committee (Central & East).

Appendix M: Letter to service user research group



Keele University

STAFFORDSHIRE
UNIVERSITY

Staffordshire and Keele Universities Doctorate in Clinical Psychology
R207, Faculty of Health Sciences,
Staffordshire University,
Science Centre, Leek Road,
Stoke-on-Trent, ST4 2DF

15th February 2013.**RE: Engagement by clinical psychologists in forensic settings study**

Dear PROSPeR SURG member,

Further to our discussions in recent PROSPeR SURG meetings, I would like to formally invite you to consult on my DClinPsy thesis project. The project seeks to find out the views of services users currently in secure care about how they might best be engaged by clinical psychologists.

To aid this process I feel it would be very valuable to consult with an experienced service user research group about the type and content of questions I will be asking, so that they are sensitive and appropriate for the intended audience. The consultation session is scheduled at Manchester University on 12th March following the scheduled SURG meeting which begins at 1pm.

Although you have all expressed an interest to me in person, and to Aisha in recent weeks, and have invited me to request your involvement, you do not have any obligation to take part. This project is not connected to the PROSPeR study, and your decision to take part will in no way affect your involvement with the PROSPeR study.

Should you wish to be involved you will be reimbursed for your consultation at a rate of £10/hour, which will be paid directly by my research budget at Staffordshire University (not from Manchester Mental Health and Social Care NHS trust as for PROSPeR).

The consultation is expected to last around one hour, where I will be asking you to look at some guide topics and questions to help me format an interview schedule. The interview schedule will be the guide I will use when interviewing the participants in the study; you will not be required to give your answers to the questions that are formatted.

I do not require any formal notification of your interest to be involved before the meeting; if you are interested please remain at the end of the SURG group, which will be held in room BO2 in the basement of Zochonis Building, Manchester University.

If you are interested in the progression of the study and any subsequent dissemination you are welcome to provide me your contact details so I can keep you informed. I also plan to continue to attend PROSPeR SURG meetings whenever possible, and to keep up to date with the progress the group is making thereof.

I look forward to seeing you all then, if you have any questions please do not hesitate to contact me directly.

Yours sincerely,

Kieran Lord
Trainee Clinical Psychologist
Staffordshire and Keele Universities Doctorate in Clinical Psychology
T: (01782) 295785
E: k.lord@keele.ac.uk / Kieran.lord@sssft.nhs.uk

Appendix N: Staff information sheet

South Staffordshire and Shropshire Healthcare 

NHS Foundation Trust

A Keele University Teaching Trust

Staff Information Leaflet

Service Users' Perceptions of Engagement by Clinical Psychologists

This leaflet is about a research project that will be conducted in the Forensic and Prison In-Reach Directorate. The study is being undertaken as part of a Doctorate of Clinical Psychology course at Staffordshire and Keele Universities by Kieran Lord. The study is expected to begin in summer 2013 and to conclude in spring 2014. Please contact Kieran Lord if you have any questions relating to the study.

What is this research study about?

In this study 'engagement' refers to the methods used by clinical psychologists and service users, when establishing therapeutic relationships. The study aims to understand what service users in secure care think about how clinical psychologists have engaged with them, and how they would like to be engaged in psychological work. We think it is important to understand service user's experiences from their perspective so that we can approach care in a way that is sensitive to their needs.

Who will be taking part in psychological work?

Service users who are currently in secure care and have experience of engagement in assessments or therapeutic work with clinical psychologists.

The study will require around twelve participants who will be over 18 years old. Participants must be able to give informed consent, and be sufficiently literate to understand the written information about the study.

What will it involve for those who choose to take part?

Service users will be invited to talk about their experiences of, and views about, engagement with clinical psychologists. The interviews will last approximately 60 minutes and will be audio recorded. The interviews will take place in a private room on site. Participants do not have to answer any questions that they do not wish to, and can withdraw from the study without giving a reason at any time.

The information that service users provide will be confidential and seen only by members of the study team. The only time that confidentiality would be breached is if it became apparent that there had been a disclosure of harm or potential harm to self or others, or criminal activity. The audio recordings will be locked securely and only available to the research team. They will be destroyed once the conversations have been transcribed and the research has been completed. Service users and staff names will not be used in any findings which may be published; some extracts taken from the tapes may be published but will have any identifying information removed.

What involvement will staff have?

Responsible clinician's will be asked to give written consent for the research team to approach individual service users directly, to provide them with information about the study and to obtain informed consent.

Following the completion of interviews staff may be asked to be available to service users to talk over any concerns that may have resulted from their involvement in the study. If staff have any concerns over the participation of any service users they should make these known to their Responsible Clinician or Dr A McGowan.

Staff will be asked about any relevant concerns about the service user prior to each interview.

What are the advantages and disadvantages of taking part?

We hope that by investigating the views of service users in secure care this will add to our knowledge about how clinical psychologists and other professions can best approach their work in future to ensure service users get the best care. We hope that it will be an opportunity for service users to have their voices heard.

We do not anticipate that the interviews will cause any distress, however, we recognise that service users may become distressed by talking about their experiences to the research team.

Do service users have to take part?

No. It is a service user's choice whether they would like to take part. After providing service users with information, they will be given at least 24 hours to consider whether they want to participate before being asked to complete a written consent form.

Can service users withdraw from the study if they change their minds?

Yes. Service users can choose to withdraw from the study at any stage and do not need to inform the researchers why.

What will happen to the information from the interviews?

The interviews will be transcribed and then analysed using the qualitative research method, IPA (Interpretative Phenomenological Analysis). The resulting themes and analysis will be submitted for publication in peer reviewed journals. Any publications will be made available to service users and staff on request. Kieran Lord will provide the Forensic and Prison-In Reach Directorate with a summary of the findings.

Who is conducting the research?

The interviews will be conducted by **Kieran Lord** (Clinical Psychologist in Training), and will be supervised by Dr Amanda McGowan (Clinical Psychologist). The study is in part being used to complete the research requirement of Kieran's doctoral training programme.

Who has reviewed this study?

This study has been peer reviewed by Keele University; it has been approved by the North Wales NHS Research Ethics Committee (Central & East); and approved by the South Staffordshire and Shropshire Healthcare NHS Foundation Trust R&D Department.

Further information

If you would like any further information please contact Kieran Lord (k.lord@keele.ac.uk, 01782 294 007).

Appendix O: Service user produced interview guide

Interview schedule – Version 2 – 10th April 2013 **South Staffordshire and Shropshire Healthcare NHS Foundation Trust**

Interview Schedule

Introduction

The CI (Chief Investigator) will introduce his role and the purpose of the research again, allowing an opportunity for the participant to ask any questions, and ensuring that the participant knows they can withdraw from the interview at any time without needing to give a reason. The ex-service user group felt it would be important to inform the participants that whilst the CI was doing the research for the purposes of an educational qualification, that they are also a professional with experience doing research, and working in forensic settings. They will be informed that although it is not expected, some of the questions may be distressing to hear or respond to, and if so, should support or advice be requested or desired, then care will be directed according to the mechanisms described in the proposal. They will be informed that they do not have to answer every question, and do not need to give a reason for this. They will be asked who they would like to be contacted (and what they feel would be useful) should the interview cause them any distress. They will be asked how they are feeling at the time of the interview.

The CI is experienced at dealing with service users in acute distress, therefore if there is any immediate distress caused by, or experienced during the interview, they would manage this initially by clarifying their concerns, and managing any risk issues, then they would consult with the service user's 24 hour care team and associated care plan, including risk assessments and management protocols.

They will be informed of confidentiality rules, and what information would involve any breaches or requirements for disclosure, and the process for this.

The questions hereafter serve as a guide for the interview and use the words that the ex-service user research group felt suitable and sensitive for purpose.

Topics

1) Clinical Psychology

Do you know what a clinical psychologist does? (Prompts: psychologist, therapist, counsellor; Inform of the role of clinical psychologist if unsure).

Have you had any experiences of working with a clinical psychologist? (Prompt: or talking therapist, counsellor).

Do you understand why you have seen one?

Have you come into any contact with clinical psychologists? (Prompt: Do you see any on the ward? Have you spoken to any in ward rounds/MDT meetings?)

What was your experience(s) of working with a clinical psychologist? (What about them made it that way?)

What do you think the difference is between clinical psychologists and other staff in secure care?
(Psychiatrists, nurses, support workers, occupational therapists)?

How are they different? (Explain differences in roles if requested or felt necessary).

2) Engagement

2.1 – Experiences of engagement

What is your understanding of the term 'engagement'? (Explain if unsure).

Who have you worked with? (Prompt: other professionals).

Do you think that it is (or could be) easier to engage with a clinical psychologist than other professions? (Psychiatrists, nurses, support workers, occupational therapists)? Why?

[If you have worked with a clinical psychologist], what was your experience(s) of engagement?*

How did you feel about them/it?

What did they make you feel like when you were working together?

How did they come across?

What were they like?

Did you work on things together? (Were your goals worked out together?)

What things were different to the way they engaged with you than other professions?

What has been your experience(s) of engagement with other professions? (Prompts as list above*).

2.2 – Optimal engagement

When you are beginning to work with someone (nurse, psychologist, doctor), what things are important to you?

How do you like to be spoken to? (Prompts: formally, by first name, using technical words, diagnoses, in a chatty way, using phrases you might use, like a doctor might)?

How should you be greeted physically (Prompts: shaking hands, smiling, sitting in a relaxed way)?

Does it matter to you how they look? (Prompts: relaxed, wearing casual clothes, formal clothes, suits, serious, casual, 'on your level')?

Where do (would) you prefer to do therapy work? (Prompts: in a quiet room, with other people, on a sofa, outside)?

How long/often do you think sessions should last? (Why?)

Without giving me names, are there any staff that you really like working with?

What is it about them that made you want to work with them?

What were they like?

Has anyone you have worked with made a difference? (If not, what was missing, or what could they have done?)

What was it doing for you? (Is it still doing anything for you?)

Were you getting something out of it?

Do you think they were doing it for your purpose? (Or for their own sake?)

How did you know that they were being real with you?

What made you feel like they were trying to help/made a difference?

If it was working, would you go again?

What was good about that person?

Did they relate to you from their own personal experience?

Were they on the same level?

How did (would) you know it was working? (What signs would you look out for? What would tell you things were getting better?)

How did (would) you know if it had been successful?

What other things do you think are important?

What things do you think make you want to continue to work with someone?

What would make you want to come back?

What might put you off?

3) Therapeutic work

How much do you like to be involved in your own care? (Prompts: do you like to have a say? do you prefer to be told? Do you prefer to work it out together?)

In what way would you like to do therapy? (Prompts: do you (or would you) like to have things structured or organised? Do you prefer to have a choice?)

Do you think that "homework" helps? (Prompts: what is it about homework that you think would not help or would help?)

Do you think that it helps for your therapist/clinical psychologist to know about your history?

Do you think your therapist should know about your offending history? (Should they ask?)

What things do you think your therapist should ask about you (or not)?

What things would you be happy to talk to your therapist about the first few times you met them? (Would that change?)

What things should your therapist not ask you in the first session or two?

What things should your therapist not ask you about at all? (Why?)

How would it make you feel about working with a therapist if they ask you these questions?

How could the therapist make you feel more comfortable? (Content, happy)

Do you think you might feel more comfortable after a period of time?

How do you know if you get on with the person you are working with? (Prompts: what things would you say you notice about people you enjoy working with?)

How do you feel if staff praise you? (Prompts: how does it feel if they complement you to others/staff/family? How do you feel when others are complimented?)

How do you like it if/when members of staff speak about your work to other staff members?

(Prompt that we are nearing the end)

4) Anything else

Is there anything related to what we have been talking about that you feel you would like to say or that might add something?

Is there anything about the way that I have been today that you feel could have been done differently? (Better? If it has been ok, what would you say has been good about the way I have been?)

Is there anything about the way I have interacted with you today that you feel was useful or different to others?

5) Further Questions

Do you have any questions about what we have talked about?

How do you feel now, after we have discussed these topics?

Is there anything that we have talked about today that has made you feel different in any way? (Further prompts about distress and risk if applicable).

Thank you for your participation.

Appendix P: Examples of line by line coding

197 Interviewer: And, Um, how did you feel when you were
198 working with her?

199

200 Hal: Um, um, actually when I come out, used to finish the
201 sessions with her, I used to come out and feel like a lot has
202 gone off my mind (ok), I've got, I've lifted a load off my mind
203 (uhum). I mean at that time, that's when I'd packed in drinking
204 for a couple of years and um, I was going to see her stone
205 cold sober, I was talking about issues in my life that affected
206 me, and, and then she sort of explained it shortly, this is
207 probably linked to that. She wouldn't go into too much detail,
208 she'd just listen good (ok), so uh that made me, that took a
209 weight off my shoulders that did.

210

211 Interviewer: Uhum, ok, umm. How did she come across?

212

213 Hal: Umm. Very placid and umm, like she wanted to listen to
214 me (ok), umm. Not like she was 'oh like not again, him
215 again with all his problems' (ok), you know, because if started
216 thinking that I wouldn't have turned up (yeah yeah ok), but
217 what happened was that I went to prison, and I lost contact
218 with her.

219

220 Interviewer: Ok, how did you get that impression of her
221 though? That that she wasn't like uh...
222

223 Hal: Yeah because umm, just the way she way, uh the way
224 she come across to me. Just a particular way
225 presenting in a particular way

226 Interviewer: yeah, and was there anything about her that
227 made you want to keep coming back?

228

229 Hal: Umm, yeah because she was a good listener (ok great)
230 and she didn't (she didn't argue, argue any points with me (ok)
231 you know. She weren't saying no, you've done that because
232 of that, she was saying, well I can understand where you are
233 coming from because of this happened, so this might have a
234 knock on effect, mentally for you to think this way and it sort
235 of, straightened my brain out if you like (ok). My way of
236 thinking (mmm) it gave me some positive things and umm,
237 she was giving me positive things, I know it sounds silly, but
238 like a simple thing that she give me was a set of traffic lights,
239 and she was on about, where I am at in them traffic lights (ok),
240 you know.

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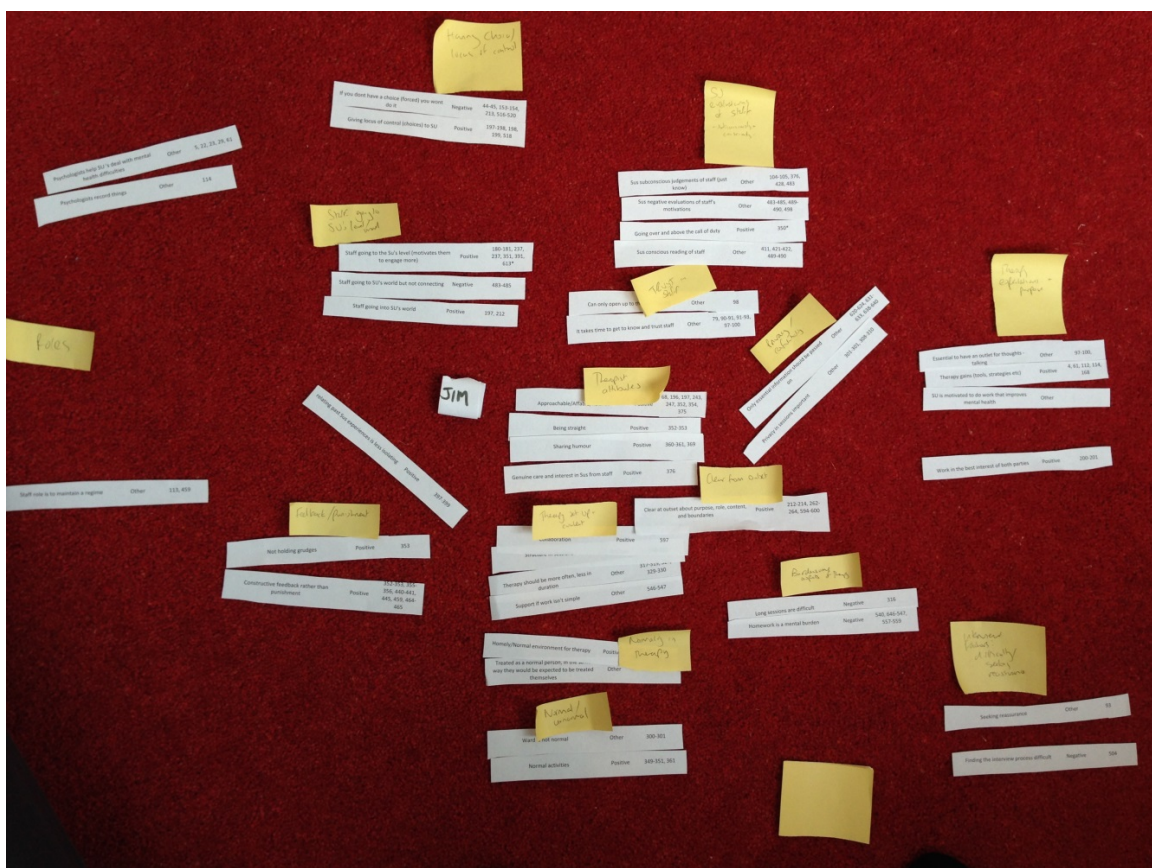
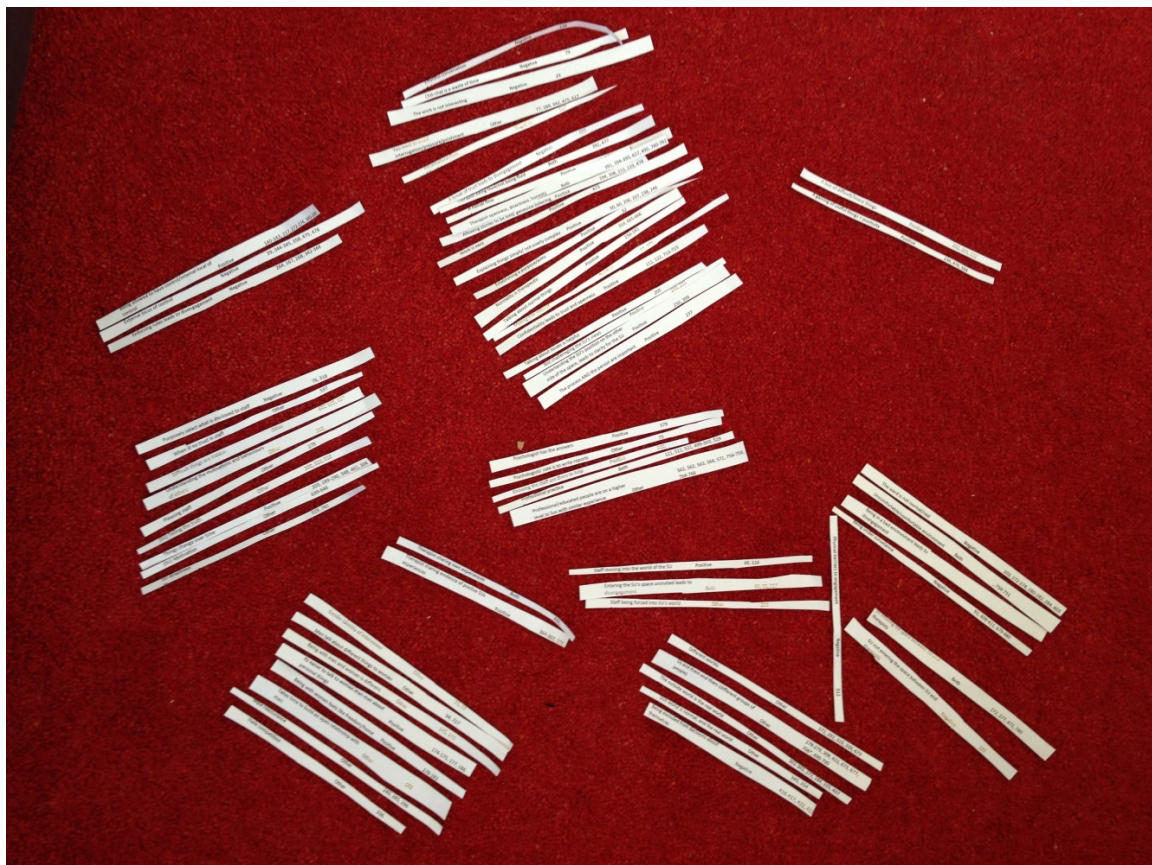
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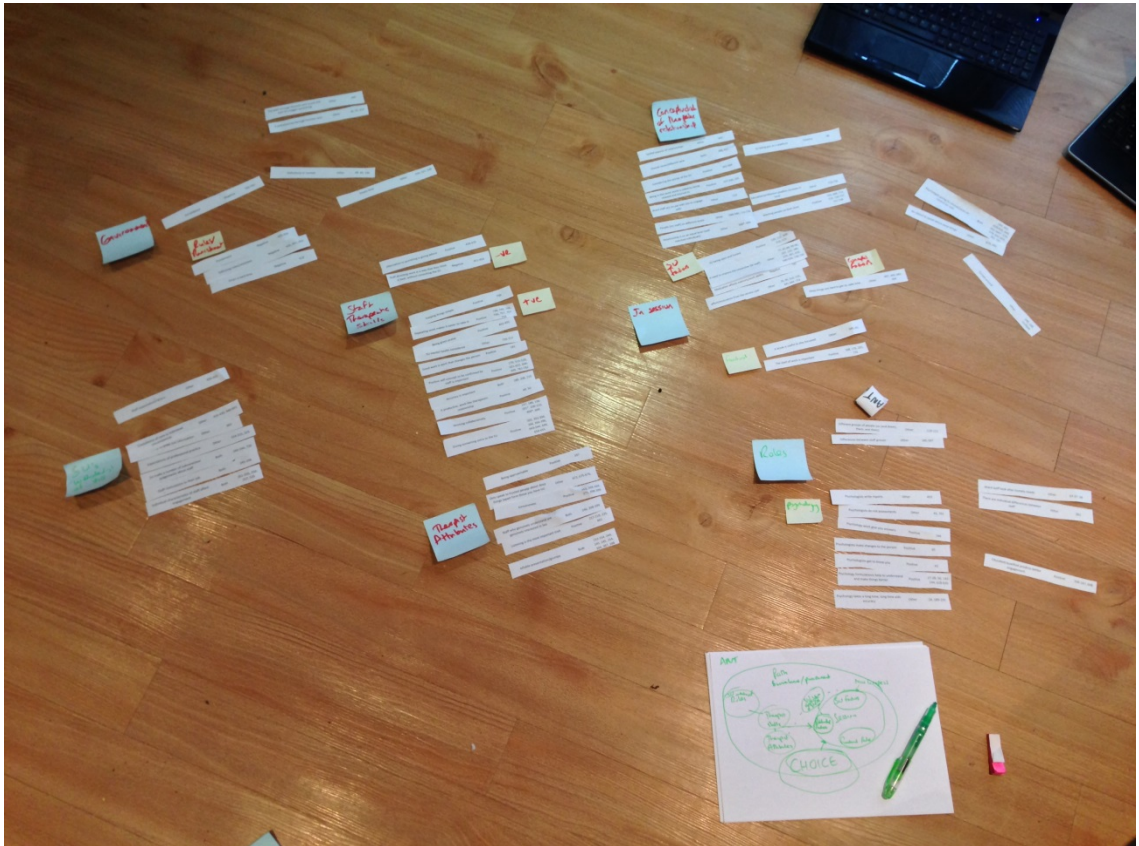
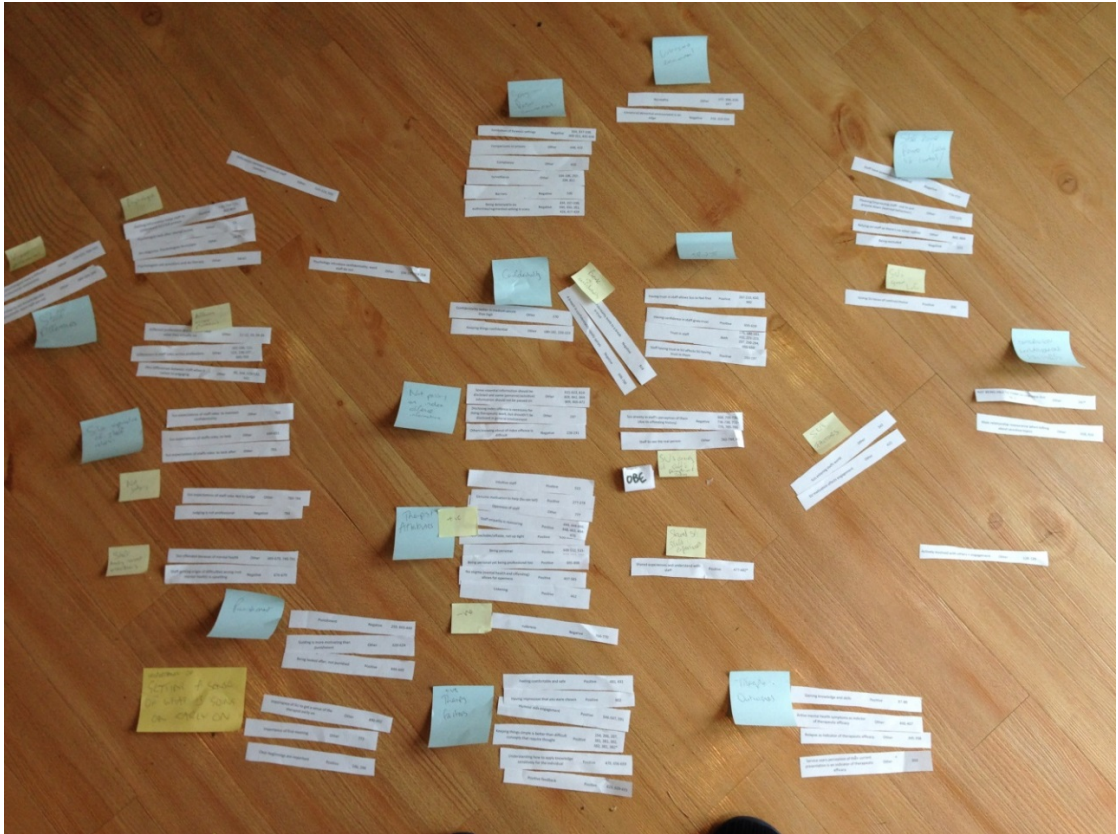
74
75 Ant: It means getting involved (ok, yeah). Yeah. Actually umm
76 doing some work and. I I use the term engage myself to try
77 and describe how I act and how I am in this unit.
78 *he engages on the unit.*
79 Interviewer: Ok, do you want to tell me a little bit more about
80 that?
81
82 Ant: Ok, yeah I do quite a bit of extra-curricular activities, as in
83 the buddy system, I'm the lead buddy for that. Recovery
84 champion, I'm the lead recovery champion as well. I attend
85 regional recovery and outcome meetings as well as in
86 the in house recovery and outcomes meeting and um and any
87 like umm when doctors come to, junior doctors come, I am
88 always put there, put up for speaking to them because of, the
89 more, how ill I was before, and how sort of normal I am, and
90 quite sensible, that it can happen to anybody at any time (mm).
91 So I am a good representative for recovery as well because
92 because my recovery through this place I have taken quite
93 seriously (uhum) and I am going to make this a life defining
94 moment. Getting schizophrenia and I was hearing voices, I really
95 was. But now I am in very good position so now I am actually
96 going to fill my potential. *has moved to a good position*
97
98 Interviewer: Excellent. That's really nice to hear.
99
100 Ant: Yeah it is...
101
102 Interviewer: ...Um. What other professionals have you worked
103 with in the sense that you might have engaged with them?
104
105 Ant: Oh well, OT staff with sports that I do, healthcares and
106 qualified nurses as in just normal day to day good relationships
107 with everybody that I turn round and meet. Good relationship
108 with the lads (mm). and umm, yeah.
109

Engaged requires effort from the SU
Impressive researcher
Staff put him on a platform
Normally (in staff's eyes) a journey/proof which proves someone's potential
Motivation (of SU)
needing to prove
Impressive (normally of relationships)
It's almost as if he is saying that the sense is normal

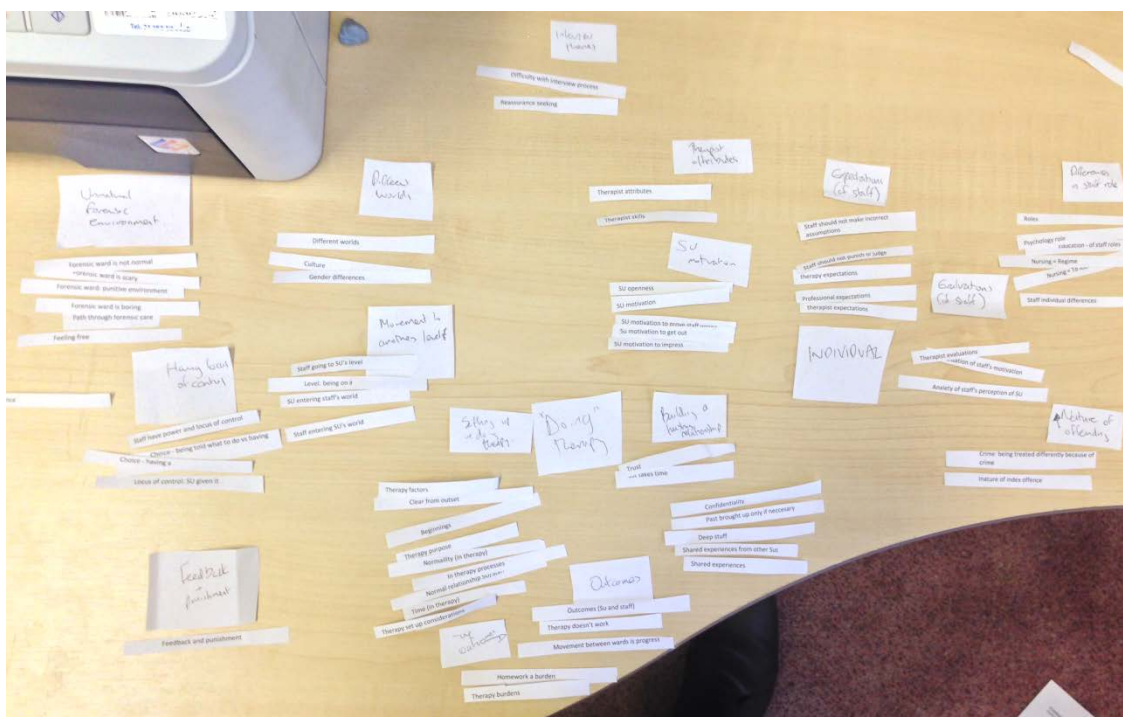
Ant has to put in some effort to be involved in engagement
Is he trying to say the right things
going the extra mile.
They use him as an example.
Staff's definitions of normal
Locus of control and personal motivation is with SU
Need to justify blame.
good relationship with everyone
Normal everyday relationships with staff

Appendix Q: Examples of diagrammatic analysis of cases





Appendix R: Examples of diagrammatic analysis across cases



Appendix S: Diagram of themes

