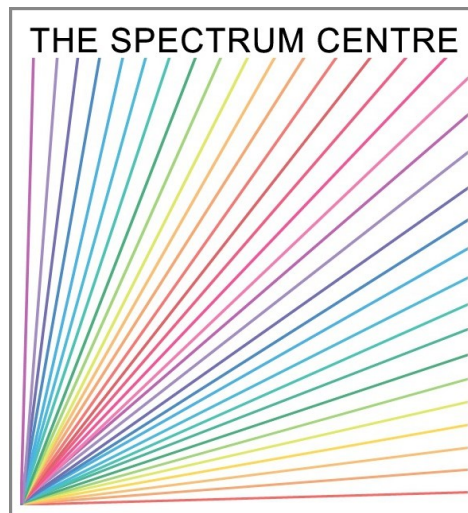


Recruitment infrastructure

A report on auditing FARSITE for use in mental health clinical research



The Spectrum Centre for Mental Health Research

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Recruitment infrastructure

The context

Spectrum Centre for Mental Health Research

The Spectrum Centre for Mental Health Research is a UK based research centre devoted to translational research into the understanding and psychological treatment of bipolar disorder and other related conditions. The Centre obtains significant grant funding from the ESRC, NIHR, MRC, and Lancaster University that enables collaborative work with third sector organisations and service users, both regionally and nationally. The Centre collaborates with NHS Trusts across England, charitable organisations, and partner Universities in the UK and abroad. Much of the Centre's research is dedicated to developing and evaluating psychological interventions for people with Bipolar Disorder, aiming not only to improve access to psychological interventions, but also choice over the types of interventions available. Current research projects involve the development and evaluation of individual, group and web based interventions.

In keeping with the public involvement agenda, Spectrum Centre employs service user researchers whose role is to lead on knowledge transfer initiatives in the community. Members of the public, service users and carers of people with mental health problems inform the Centre's research activities and priorities via the Advisory Panel.

Clinical Research Network

Recently renamed from Comprehensive Local Research Network, the Clinical Research Network (CRN) provides the infrastructure to enable the delivery of clinical research in the NHS. The CRN provides support to researchers in the process of setting up clinical studies; helps the life-sciences industry to deliver their research programmes; offer research training to health professionals; and ensures that the needs of patients are reflected across all clinical research activity. Also, the CRN runs the NIHR Coordinated System for gaining NHS Permission (CSP) – a system through which researchers can apply for permission to run a clinical study in the NHS; funds research support posts in the NHS; supports researchers financially by meeting the costs of using facilities such as scanners and x-rays; and plays an important role in identifying and recruiting patients onto Portfolio studies. The CRN currently consists of 15 Local Clinical Research Networks (see figure 1).

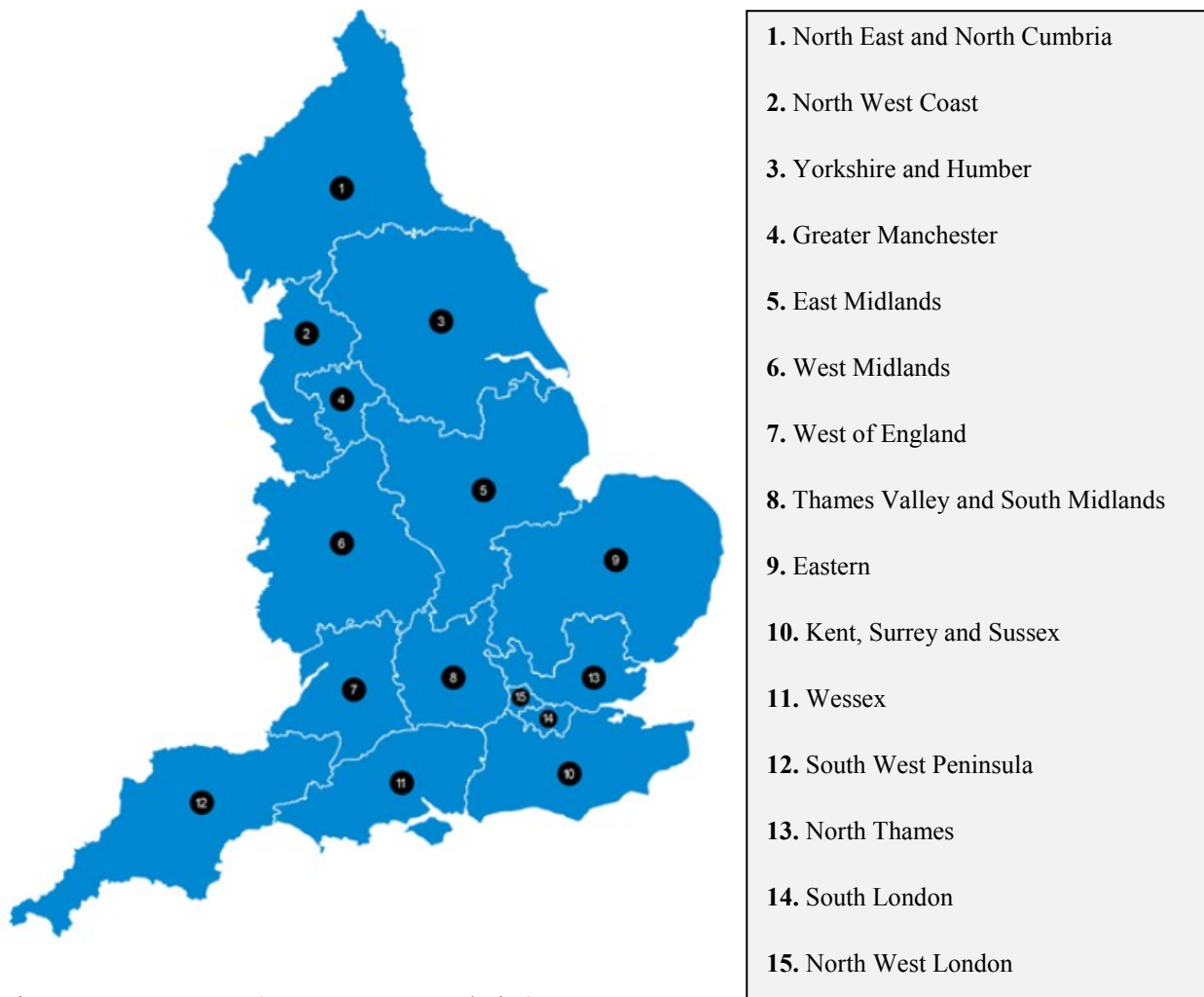


Figure 1. CRN map (source: CRN website)

The Spectrum Centre works in partnership with North West Coast CRN to develop the infrastructure around recruitment of people with mental health problems via primary services.

The problem

Typically, clinical research has focused on recruiting individuals actively engaged in mental health services and this may lead to a bias in the outcomes (limited generalisability of findings). Primary care is an important source of recruitment. It allows access to individuals who may be functioning relatively well (i.e. not involved in secondary care services) – but may still be interested in participating in an intervention study. They may still want/ benefit from additional support.

Solution

North West E-Health (NWEH) developed FARSITE (Feasibility And Recruitment System for Improving Trial Efficiency); a specially designed software to assist in identification and recruitment of participants for clinical trials. The developers suggest that FARSITE aims to increase efficiency and accuracy of study recruitment; preserve individual consent, protect patient privacy (researchers only access anonymised and aggregated data); share knowledge about the way medical data is recorded. The developers suggest that FARSITE is an effective mechanism in identifying potential research participants and design recruitment strategies accordingly. Since March 2014 NWEH has established a collaboration with local AHSNs to involve primary and secondary care teams. NWEH will provide FARSITE to 50 GP practices in each of the AHSNs. The licence with local AHSNs to use FARSITE will run until April 2016. Researchers can access FARSITE for free via the CRN. Subject to funding, NWEH plans for the future is to expand the data currently available, which are limited to Lancashire and Cumbria, with data from GP Practices in Liverpool.

Figure 2 show the process by which individual patients who meet inclusion criteria for a particular research project are being identified.

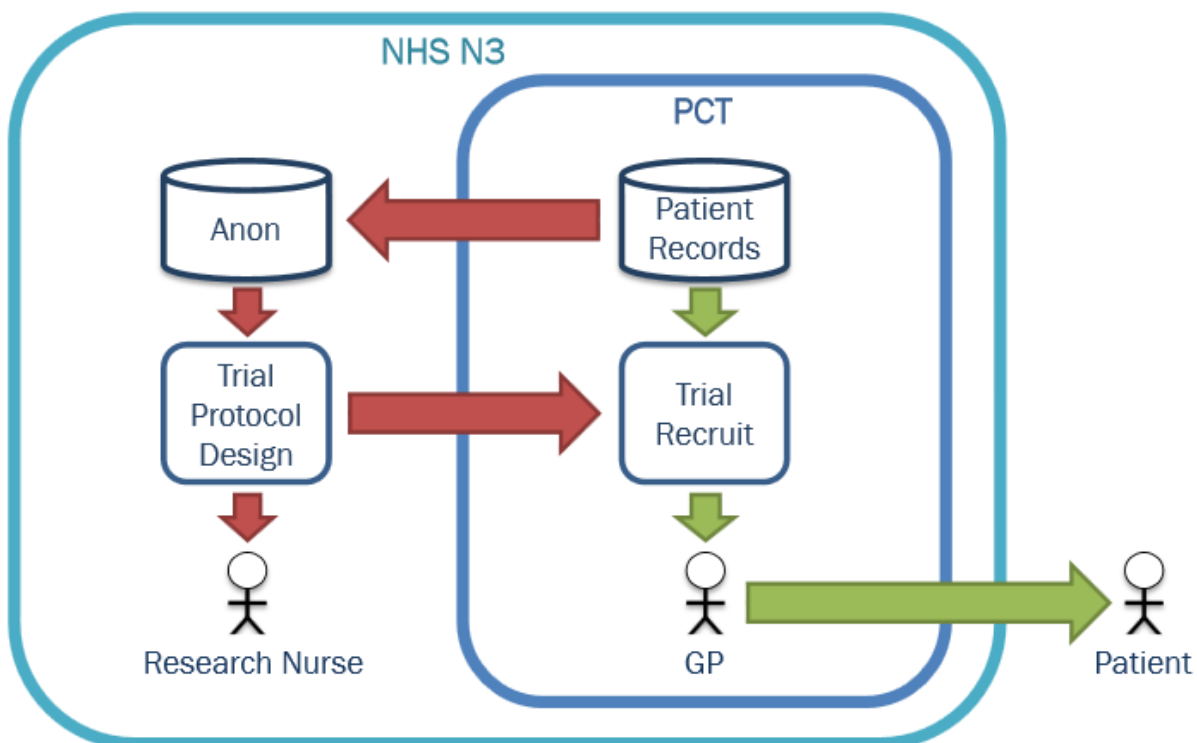


Figure 2. Identifying patients in FARSITE

Lessons Learned

Identifying participatory GP practices

In the process of auditing FARSITE for use in mental health clinical research, we performed a search of people with BD across the CRN North West Coast footprint (i.e. Cumbria and Lancashire) with the view to develop a map of the area and target recruitment strategies accordingly. The snapshots in at the end of this report show the steps undertaken (Figure 4 – Figure 10).

Results

Fifty GP practices registered with FARSITE across the CRN North West Coast were included in the search. The total number of patient population across these practices was 320,947. Out of these 50, people with BD were identified in 36 GP practices. Based on the national prevalence rates for BD we should expect approximately $320,947 * 1.5\% = 4814$ people to be identified. However, the total number of adult with BD (18 and over) that identified were 788. Based on these figures the prevalence of BD in these GP practices is approximately 0.245%, which is far lower from the national average. Note that in the search we used the generic code Bipolar Disorder which includes all BD types and related experiences. These 788 people identified do not represent the total number of people with BD who live in the region, as a significant number of those would be seen by secondary psychiatric services and local authorities and would be treated either in the community or psychiatric hospitals. These people could not have been identified in a FARSITE search. Also, evidence from the UK suggests that between 3.3% and 21.6% of primary care patients with unipolar depression may have an undiagnosed bipolar disorder (Smith, et al., 2011). Yet again, these people would not be included in the results. Despite these limitations, the total number of participants identified still warrants targeted recruitment strategies that would provide these people the choice of accessing interventions that are delivered in the context of research.

To obtain a summary of the distribution of people with BD across the practices (center and spread) we calculated the interquartile range (IQR). 10 GP practices were below Q1 with a total of 71 people with BD (Q1=10.5). 9 practices were below Q2 with a total of 125 people (Q2=15). 9 practices were below Q3 and had records of 208 people with BD (Q3=27). Finally, there were 8 practice above Q3 and had a total of 386 people with BD. The list of GP practices, including their postal address, appears in Table 1 in ascending order from 1 to 36, based on the number of records of people with BD available. The geographical location of the identified practices is noted in Figure 3. The colours

of the pins represent frequency of occurrence of records of people with BD in each practice, and are grouped according to the IQR. Values above Q3 is red (GP practices: 1-8); valued above Q2 is blue (GP practices: 9-17); values above Q1 is green (GP practices: 18-26) and values below Q1 is yellow (GP practices: 27-36).

Plotting the data on the map aimed to potentially visually identify disproportionate density of people with BD in particular regions. The results do not allow geographical distributions inferences to be drawn as GP practices from the same or neighbouring regions appear to have significantly different number of records of people with BD. One possible explanation of this difference could be the degree to which the health records in each practice are up to date. Another possibility could be the difference in skills in identifying BD by the health teams in each practice. This is in keeping with the increase rate of undiagnosed cases of BD (Smith et al., *ibidem*).

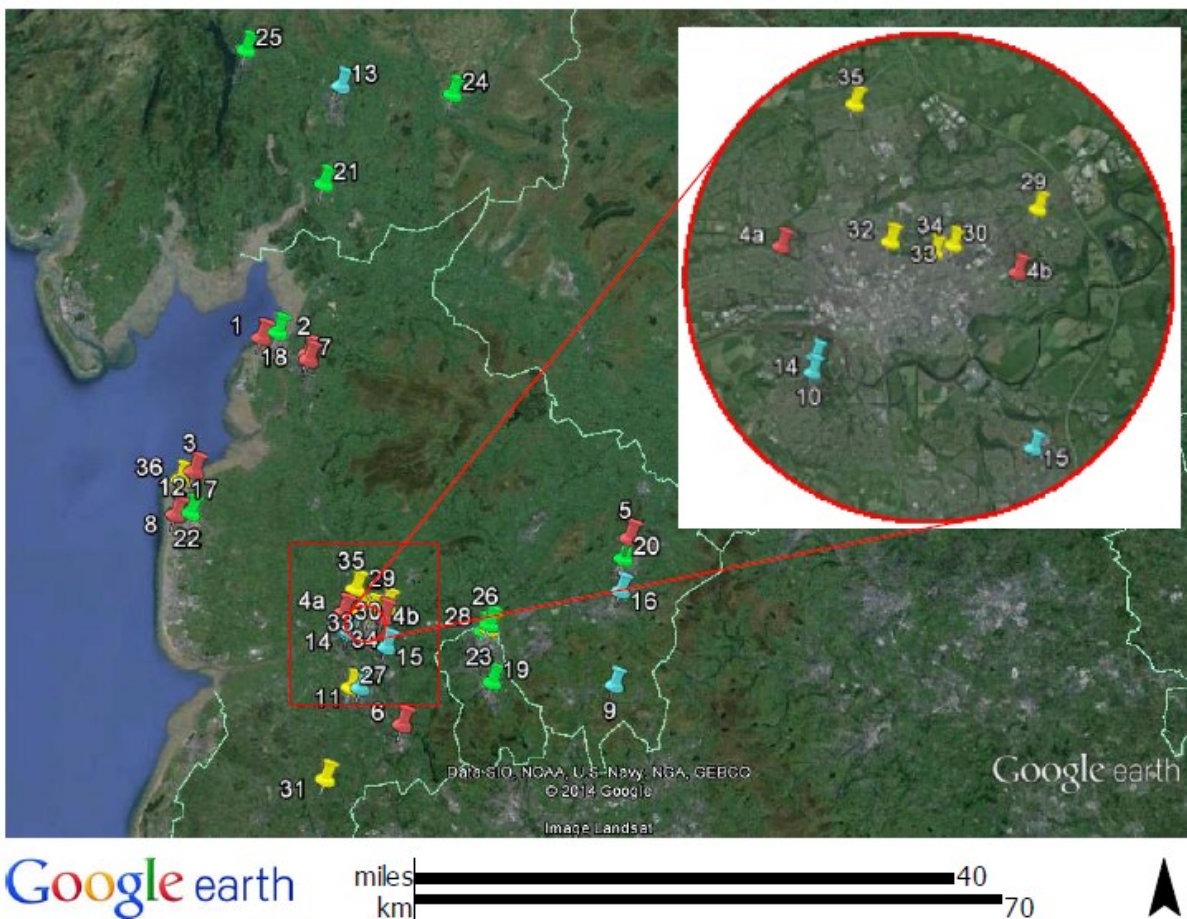


Figure 3. Map of GP Practices with people with BD across the North West Coast.

Recruitment Estimate broken down by practice.				
No	Practice Identifier	GC Practice	Key person and Address	No of ppl with BD
1	Y01008	Coastal Medical Group	1 Heysham Rd, Morecambe, Lancashire, LA3 1DA 0845 634 5634	94
2	P81013	Queen Square Medical Practice	2 Queen Square, Lancaster LA1 1RP 01524 843333	53
3	P81089	Mount View Practice	Fleetwood Health and Wellbeing Centre, Dock St, Fleetwood FY7 6HP 01253 951999	50
4	P81664	The Park Medical Centre (Eyre)	01772 726500 a. Cottam Lane Surgery, Cottam Lane, Ashton, Preston, Lancashire PR2 1JR b. New Hall Lane Surgery, 370 New Hall Lane Preston, PR1 4SX	43
5	P81032	Reedyford Health Care Barrowford Health Centre	Lee St, Barrowford, Nelson, Lancashire BB9 8NR 01282 657575	41
6	P81044	Library House Surgery	Library House, Avondale Rd, Chorley, Lancashire PR7 2AD 01257 262081	40
7	P81056	Rosebank Medical Practice	Ashton Rd, Lancaster, Lancashire LA1 4JS 01524 842284	33
8	P81073	Cleveleys Group Practice	Kelso Avenue, Thornton-Cleveleys, Lancashire FY5 3LF 01253 853992	32
9	P81132	Waterfoot Group Of Doctors	Waterfoot Group of Doctors Cowpe Road, Waterfoot, Rossendale BB4 7DN	27
10	P81213	St Marys Health Centre	Cop Ln, Penwortham, Preston, Lancashire PR1 0SR 01772 644151	27
11	P81057	Worden Medical Centre	West Paddock, Leyland PR25 1HR 01772 423555	25
12	P81092	The Crescent Surgery	Kelso Ave, Blackpool, Thornton-Cleveleys, Blackpool FY5 3LF 01253 823215	25

13	A82027	Station House Surgery	Station Rd, Kendal, Cumbria LA9 6SA 01539 722660	24
14	P81018	St Fillan's Medical Centre	2 Liverpool Road Penwortham, Preston PR1 0AD	22
15	P81083	Roslea Surgery	51 Station Rd, Bamber Bridge, Preston PR5 6PE 01772 310100	20
16	P81020	St Nicholas Group Practice	St Peters Centre, Church St, Burnley, BB11 2DL 01282 644222	20
17	P81086	Broadway Medical Centre	West View Health Village, Broadway, Fleetwood FY7 8GU 01253 657500	18
18	P81085	Dr S E Brear & Partners (Yorkbridge)	York Bridge Surgery, 5 James St, Morecambe LA4 5TE 01524 831111	15
19	P81140	Darwen Health Centre	James St W, Darwen, Blackburn with Darwen BB3 1PY 01254 226691	15
20	P81070	Pendle View Medical Centre	47 Arthur St, Brierfield, Nelson BB9 5RZ 01282 614599	14
21	P81046	Park View Surgery	Haverflatts La, Milnthorpe LA7 7PS 015395 63327	14
22	P81133	The Village Practice (Thornton Medical Centre)	Church Rd, Thornton-Cleveleys, Lancashire FY5 2TZ 01253 854321	14
23	P81607	The Montague Practice	Barbara Castleway Health Centre, Simmons Street, Blackburn, Lancashire BB2 1AX 01254 617201	14
24	A82608	Sedbergh Medical Practice	Station Road, Sedbergh, Cumbria, LA10 5DL	14
25	A82046	Windermere Health Centre	Goodley Dale, Windermere LA23 2EG 015394 45159	14
26	P81622	Bangor Street Health Centre (Shifa)	Blackburn, Lancashire, BB1 6DY 01254 617440	11

27	P81186	Moss Side Medical Centre	16 Moss Side Way, Leyland, Lancashire, PR26 7XL 01772 623954	10
28	P81771	Primrose Bank Medical Centre	Primrose Bank, Blackburn BB1 5ER 01254 672132	10
29	P81184	Ribbleton Medical Centre	243 Ribbleton Avenue, Preston Lancashire, PR2 6RD 01772 792 512	10
30	P81196	Issa Medical Centre	73 St Gregory Rd, Preston PR1 6YA 01772 798122	9
31	P81096	Parbold Surgery	4 The Green, Parbold, Lancashire WN8 7DN 01257 514000	7
32	P81152	Drs G A & A Robb	The Surgery, 63-65 Garstang Rd, Preston PR1 1LB 01772 253554	6
33	P81705	Issa Medical Centre	73 St Gregory Rd, Preston PR1 6YA 01772 798122	5
34	P81647	Dr J N Jha	310A St George's Rd, Preston PR1 6NR 01772 254546	5
35	P81691	Beech Drive Surgery	17-19 Beech Dr, Fulwood, Preston PR2 3NB 01772 863033	5
36	P81690	Belle Vue Surgery	Belle Vue Surgery/Broadway, Fleetwood, FY7 8GU 01253 657575	2

Table 1. Recruitment Estimate broken down by practice.

Approaches and liaisons with GP practices

Once identified on the FARSITE, the researcher can contact each GP practice directly via the platform, by uploading supporting documents that would enable GPs to inform potential participants about the research.

The identification of individual potential participants is usually a staged approach and depending on the level of involvement of the researcher it may require several visits to a practice.

1. Records are searched (by a GP/ research nurse)
2. Specifically for Spectrum, this list would need to be cross checked against people who might already be involved in other intervention studies currently being rolled out by Spectrum.
3. The list is circulated to treating practitioners for them to say 'yes' or 'no' to their patient being contacted

4. The invitation letters are printed on practice stationary/ including the practice letter head
5. The invitation letters are circulated to treating practitioners (or a single GP – depending on practice preference) to co-sign
6. Letters are sent

So far, it has not been possible to identify the exact number of participants who have been referred to Spectrum studies via participatory GP practices. In fact, previous attempts to liaise with GP practices have been variably successful. The reasons behind this are not clear. But, the resistance in referring people who meet inclusion criteria into studies could potentially be explained by a number of reasons.

1. Spectrum is currently not holding specific information of referrals from primary care. Categorisation of referrals is limited to i. self-referrals, and ii. secondary care (with information on specific Trusts or individual care coordinator who refers participants). In effect, primary care referred participants' figures would have been missed. This does not apply to one of Spectrum studies (Recovery CBT), where 25% of all participants in the study were recruited via primary care services.
2. The GP practices who had originally signed up to FARSITE were led by clinicians who were research active and who would have signed a service level agreement to support research with specific obligation to recruit participants to time and target. It is not currently clear, however, how many of the original participatory GP practices still have the service level agreement. Many individuals from these GP practices have moved on and it is unclear whether those who came on board share the same interest on research. It is also unclear whether those who did meet the recruitment targets were remunerated for doing so.
3. Despite the fact that as of March 2014 NWEH successfully won the bid to Health e-Research Centre to supply healthcare data appliances to three AHSN's in the north of England (Greater Manchester, North West Coastal and North East and North Cumbria), the NIHR appears to support a different platform, which might have had negative impact on FARSITE's usability. The new service is the Clinical Practice Research Datalink (CPRD) and is jointly funded by the NIHR and the Medicines and Healthcare products Regulatory Agency. The developers of CPRD services suggest that CPRD is designed to support observation research and delivery of research outputs that are beneficial to improving and safeguarding public health by linking NHS clinical data. So far, the usage of CPRD has resulted in over 890 clinical reviews and papers. To use this service, legal agreements need to put in place and service costs are priced

taking into consideration time of staff required and use of specific IT systems. The cost for accessing the service is not currently publically available.

Conclusion

This report set out to identify strategies for recruiting people with mental health problems in research project via primary care. Our review of the infrastructure available showed that there are currently tools available that enable the identification of GP practices that would support clinical research with people with mental health problems who would historically be identified via secondary care services.

There are currently at least two systems that support such work to be carried out (FARSITE & CPRD). Since CPRD requires significant funding to access the data, for the purpose of this report we audit FARSITE which can be accessed for free. In the hypothetical search strategy we performed for a research project with people with BD, we found that there were 788 adults with BD in Lancashire and Cumbria. Whilst this is a significantly smaller number of people than what one would expect based on epidemiological data, it is still a large enough population sample that should not be ignored from recruitment strategies. A 10% success rate in recruiting people into research projects from this sample would result in almost 80 people. Including people with mental health problems currently been treated by primary care services in clinical trials would significantly increase generalisability of findings and most importantly offer treatment options to a larger number of people.

Several challenges in accessing or using the platforms available have been identified and discussed. Whilst budgeting for resources needed when applying for funding, academics should consider factoring in the resources needed for accessing such platforms.

Figure 4

Step 1: Create a new study and insert relevant descriptors.

NWEH
NorthWest EHealth

Farsite Home | Reports | Common Criteria | Organisations | Clinical Codes Browser | Help

Options

- ▶ Return to list of studies

New Study Details

Study Name: *

Short Description:

Study Type: ▾

Funding: ▾

Use Docmail? ⓘ

The NIHR Comprehensive Local Research Network

- ▶ Cumbria and Lancashire CLRN ⓘ

* Denotes required fields.

Figure 5

Step 2: Insert relevant fields

The screenshot displays the NWEH (NorthWest EHealth) interface. At the top, there is a navigation bar with links for Farsite Home, Reports, Common Criteria, Organisations, Clinical Codes Browser, and Help. On the left side, there are two sidebar panels: 'Options' and 'Study Overview'. The 'Options' panel contains links for creating new studies, copying studies, canceling studies, exporting studies, and returning to a list of studies. The 'Study Overview' panel shows the current study's state as 'Feasibility' and lists 'The NIHR Comprehensive Local Research Network' with an edit link and a link to 'Cumbria and Lancashire CLRN'. Below this, it lists 'Study Members' including 'Nicola Dooley (Creator)'. The main content area is titled 'Bipolar PT' and has two tabs: 'Description' (selected) and 'Protocol'. The form fields are as follows:

Study Name	<input type="text" value="Bipolar PT"/> *
Short Description	<input type="text" value="Bipolar PT"/>
UKCRN ID	<input type="text"/>
Research Network Code	<input type="text"/>
Study Type	<input type="text" value="Interventional And Observational"/>
Funding	<input type="text" value="Non-commercial"/>
Use Docmail?	<input type="checkbox"/>

* Denotes required fields.

Next

Figure 6

Step 3: State inclusion/exclusion criteria

The screenshot shows the NWEH (NorthWest EHealth) web application interface. At the top, there is a navigation bar with links for 'Farsite Home', 'Reports', 'Common Criteria', 'Organisations', 'Clinical Codes Browser', and 'Help'. On the left side, there are two sidebar menus: 'Options' with links like 'Create new study', 'Create copy of this study', 'Cancel study', 'Export Study', and 'Return to list of studies'; and 'Study Overview' with sections for 'State' (Feasibility), 'The NIHR Comprehensive Local Research Network (Edit)', 'Cumbria and Lancashire CLRN', and 'Study Members' (Nicola Dooley (Creator)).

The main content area is titled 'Bipolar PT' and has two tabs: 'Description' and 'Protocol'. Below the tabs, it says 'You saved the study on 27/10/2014 11:54:45'. There are 'Back' and 'Save' buttons. The 'Inclusion Criteria (Match All Include Groups Change)' section contains a list with one item: 'Include: one'. A yellow highlight says 'Click on 'Add Criteria' button to add criteria to this group'. Below this are 'Add Criteria' and 'Add Include Group' buttons. The 'Exclusion Criteria' section has an 'Add Exclude Group' button. The 'Demographics' section includes fields for 'Lower Age' and 'Upper Age' (both set to '--' Years), a 'Gender' dropdown set to 'Any', and checkboxes for 'Ethnicity' (Any, White, Mixed, Asian or Asian British, Black or Black British, Other) and 'Smoker' (Any, Current Smoker, Ex-Smoker, Never Smoked). 'Back' and 'Save' buttons are also present at the bottom of the demographics section.

Figure 7

Step 4: Insert search terms

The screenshot shows the NWEH (NorthWest EHealth) interface. At the top, there is a navigation bar with links for 'Farsite Home', 'Reports', 'Common Criteria', 'Organisations', 'Clinical Codes Browser', and 'Help'. On the left, there are two main sections: 'Options' with links like 'Create new study', 'Create copy of this study', 'Cancel study', 'Export Study', and 'Return to list of studies'; and 'Study Overview' with 'State' (Feasibility) and 'The NIHR Comprehensive Local Research Network (Edit)'. The main content area is titled 'Bipolar PT' and includes sections for 'Inclusion Criteria', 'Exclusion Criteria', and 'Demographics'. A search modal is open in the center, showing a search bar with 'Bipolar' entered and a 'Search' button. The modal has a progress indicator at the top with 'Search' highlighted, followed by 'Results' and 'Restrictions'. Below the search bar, there is a 'Hide Advanced Options' section with radio buttons for 'Match whole word' (selected) and 'Match anywhere within word'. Below this, there are instructions: 'Search multiple items using OR, e.g. Diabetes OR Diabetic', 'Exclude items using NOT, e.g. Metformin NOT Sitagliptin', 'Perform a single character wildcard search using "?"', 'Perform multiple character wildcard search using "**"', and 'Perform a fuzzy search, to find similar spellings, using "~"'. There is also a 'Search By Read Code' button and a 'Close' button at the bottom of the modal. A note at the bottom of the modal states: 'This search uses the SNOMED Clinical Terms (UK Release) Dataset. Results are limited to the first 200 terms.'

Figure 8

Step 5: Results based on the search terms inputted (limited to the first 200 terms)

The screenshot shows the NWEH (NorthWest EHealth) interface. The main header includes navigation links: Farsite Home, Reports, Common Criteria, Organisations, Clinical Codes Browser, and Help. The left sidebar contains 'Options' (Create new study, Create copy of this study, Cancel study, Export Study, Return to list of studies) and 'Study Overview' (State: Feasibility, The NIHR Comprehensive Local Research Network, Cumbria and Lancashire CLRN, Study Members: Nicola Dooley (Creator)).

The main content area is titled 'Bipolar PT' and shows a search process. A modal window is open, displaying the search results. The modal has three tabs: 'Search', 'Results', and 'Restrictions'. The 'Results' tab is active, showing a list of diagnoses from the SNOMED Clinical Terms (UK Release) Dataset. The list includes:

- Bipolar disorder (X00SM) ★★☆☆
- Bipolar disorder (Eu31) ★★☆☆
- Bipolar I disorder (XUUqa) ★★☆☆
- Bipolar disorder in remission (XUMlo) ★★☆☆
- Mild bipolar disorder (XUTVm) ★★☆☆
- Moderate bipolar disorder (XULA2) ★★☆☆
- Mixed bipolar affective disorder (E116) ★★☆☆
- Organic bipolar disorder (X00RO) ★★☆☆

The modal also includes a 'Close' button and navigation buttons for 'Back' and 'Next'. A note states: 'This search uses the SNOMED Clinical Terms (UK Release) Dataset. Results are limited to the first 200 terms.'

Figure 9

Step 6: Define time period (none in our case)

The screenshot shows the NWEH (NorthWest EHealth) web application interface. The main navigation bar includes 'Farsite Home', 'Reports', 'Common Criteria', 'Organisations', 'Clinical Codes Browser', and 'Help'. The left sidebar contains 'Options' (Create new study, Create copy of this study, Cancel study, Export Study, Return to list of studies) and 'Study Overview' (State, Feasibility, The NIHR Comprehensive Local Research Network (Edit), Cumbria and Lancashire CLRN, Study Members: Nicola Dooley (Creator)).

The main content area is titled 'Bipolar PT' and shows a 'Description' tab. A modal dialog box is open, titled 'Restrictions', with a progress bar showing 'Search' > 'Results' > 'Restrictions'. The dialog contains the following options for 'Diagnosis Made':

- Any time period
- Time period was Between Months And Months Ago
- Exact date was Between And
- Between months And for any year

At the bottom of the dialog are 'Back' and 'Finish' buttons. A 'Close' button is also visible in the bottom left corner of the dialog.

Figure 10

Step 7: Search Results

NWEH
NorthWest EHealth

Farsite Home | Reports | Common Criteria | Organisations | Clinical Codes Browser | Help

Options

- ▶ Create new study
- ▶ Create copy of this study
- ▶ Cancel study
- ▶ Export Study
- ▶ Return to list of studies

Study Overview

State
Feasibility

The NIHR Comprehensive Local Research Network (Edit)

- ▶ Cumbria and Lancashire CLRN

Study Members

- ▶ Nicola Dooley (Creator)

Bipolar PT

Description | Protocol

You saved the study on 27/10/2014 11:54:45

View Protocol History

Edit Run Approve

Protocol took 5.107 seconds to run.

Population Total 320,947 people

Inclusion Criteria (Match All Include Groups)

Include: one (Running Total) 788 people

Running Total (with duplicate matches removed) 788 people

Exclusion Criteria

Running Total (with duplicate matches removed) 788 people

Demographics

Age is greater than 18	(Running Total) 788 people
Gender is Any	788 people
Ethnicity: Any	788 people
Smoker types: Any	788 people

Recruitment Estimate 788 people

Edit Run Approve

Back

References

Smith, D. J., Griffiths, E., Kelly, M., Hood, K., Craddock, N., & Simpson, S. A. (2011). Unrecognised bipolar disorder in primary care patients with depression. *Br J Psychiatry*, *199*, 49-56.