Outcome Measurement in Psychological Services: A Systematic Review & Empirical Study

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Chapter 1

A systematic review of the effects of routine structured feedback on client progress in individual psychological therapy

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Abstract

Purpose: This systematic review aimed to establish if continuous structured feedback, in the context of individual psychological therapy within psychiatric/mental health settings can improve treatment effectiveness and efficiency compared to treatment as usual/no feedback, and if the effects of feedback are influenced by feedback recipient, type, a Clinical Support Tool (CST) or clinician training.

Methods: A systematic literature search was undertaken in key databases. The quality of key papers were assessed using a critical appraisal tool. A narrative synthesis approach was used to summarise findings.

Results: The search generated 15 papers. Structured feedback was found to be superior to a comparator in half of studies ($d = .26$, $d = .49$). For initial treatment non-responders, 3/10 studies found feedback to be superior ($d = .12$, $d = .23$). Only 3/9 studies found structured feedback improved efficiency ($d = .22$). However, there were limitations around how efficiency was measured. Feedback to clinician and client may be superior to clinician alone and CSTs may be effective for initial treatment non-responders.

Conclusions: Structured feedback can improve treatment effectiveness in individual psychological therapy in clinical populations, but findings are not consistent. How feedback is implemented needs to be considered.

1. Introduction

1.1 Background

With increasing population rates of psychological distress, effective and efficient mental health interventions are needed more than ever (Zhang et al., 2023). The effectiveness of psychological therapy is well evidenced (e.g. The Matrix; Scottish Government, 2023). However, in naturalistic settings, it is estimated 50% of clients will not experience significant treatment gains (Hansen & Lambert, 2003), with 5-10% experiencing a worsening in their difficulties (Hansen et al., 2002).

Clinicians struggle to identify clients who are not progressing in therapy (Hatfield et al., 2010). Structured feedback on client progress could improve outcomes (Waller & Turner, 2016). Structured feedback involves the routine use of Patient Reported Outcome Measures (PROMs), with timely feedback provided to the clinician (and sometimes client) on current versus expected progress. Expected progress is based on norms for trajectories of change (Lambert, 2012). Structured feedback can be implemented using PROMs alone or via feedback systems such as the Outcome Questionnaire, OQ-Analyst (Lambert et al., 2010) and the Partners for Change Outcome Management System, PCOMS (Duncan, 2012). Feedback can include process (related to therapeutic processes) alongside progress feedback. Graphed scores on PROMs are often provided, accompanied by an Expected Treatment Response ("ETR") curve and signals/messages to convey the clients' level of progress, highlighting treatment non-responders, referred to as those 'not on track' ("NOT"). NOT indicates a clients' scores have deviated significantly and negatively from the ETR. Clinical Support Tools (CSTs) are sometimes available for use with those NOT, incorporating measures to identify barriers to progress, treatment guidance, and resources (Lambert et al., 2007).

1.2 Current Evidence

The effectiveness of structured feedback has been investigated in populations across the lifespan (Bergman et al., 2018; Gondek et al., 2016), with different client groups (Davidsen et al., 2017; Schuman et al., 2015), in outpatient (Tzur Bitan et al., 2020), inpatient (Puschner et al., 2009) and crisis settings (van Oenen et al., 2016). Structured feedback has been delivered

in the context of a range of mental health interventions such as pharmacotherapy and guided self-help (van Oenen et al., 2016). For psychological therapy, studies have examined individual (Amble et al., 2015), group (Hutson et al., 2020) and couples therapy (Anker et al., 2009) formats. Findings from empirical studies have been mixed, varying from no effect of feedback (Davidsen et al., 2017), a significant but small effect (Schuman et al., 2017, d =.28), to a significant medium effect (Anker et al., 2009, d =.50). This may reflect the variability in sample populations, feedback used and study quality.

A meta-analysis by Knaup et al. (2009) looked at the use of structured feedback in 12 studies in adult mental health services and concluded feedback was associated with greater treatment effectiveness as measured by changes on symptom scores, with a small effect size (d = .10). No differences were reported in efficiency. However, a subsequent systematic review incorporating 32 studies conducted across mental health settings (Gondek et al., 2016) found only 56% of studies showed a significant positive effect of feedback, with 20% demonstrating improved treatment efficiency.

Davidson et al. (2015) undertook a systematic review of 11 studies examining the use of continuous structured feedback specifically in the context of individual psychological therapy, concluding feedback improved treatment effectiveness for NOT clients .However, 60% of the included studies were conducted with university students, with one third of the sample having symptoms below clinical thresholds. The authors stated it was therefore unclear if structured feedback could improve therapy outcomes for clients in psychiatric/specialist mental health settings such as those in the National Health Service (NHS) in the UK. Further research in psychiatric settings has since been undertaken (e.g. Brattland et al., 2018).

De Jong et al. (2021) undertook a recent meta-analysis of structured feedback in psychological therapies involving 58 studies. They found a small effect for treatment effectiveness (d = .15) but no effect for treatment efficiency when comparing structured feedback to control groups. However, this meta-analysis included any psychological therapy format (e.g. group, individual) and various intensities of structured feedback (the minimum being three occasions where feedback was provided). They also excluded studies with clients experiencing "severe mental illnesses". Whether continuous (session by session) structured feedback specifically in

individual psychological therapy within adult psychiatric/mental health settings is effective is unclear. In addition, treatment efficiency within the meta-analysis was based on the number of sessions attended, a trend across studies in this area. There is evidence structured feedback may reduce dropout for NOT clients, increasing sessions attended, and shorten treatment duration for 'on track' ("OT") clients (Shimokawa et al., 2010). This has the potential to cancel out overall differences when number of sessions is compared between feedback and non-feedback groups. Measuring efficiency in other ways is needed.

The mechanisms through which structured feedback might work also remains unclear (Gondek et al., 2016). Contextualised Feedback Intervention Theory (Riemer & Bickman, 2011) suggests feedback directs the clinician's attention towards the goal(s) of therapy and the client's progress in comparison, motivating clinicians to adapt their work when there are discrepancies. This suggests feedback may be most beneficial for those NOT (de Jong et al., 2014).

1.3 Potential Moderators

Variations in how feedback is implemented, such as the feedback recipient, content of feedback and whether CSTs are used, may influence the effect of structured feedback. The extant literature with regards to these will now be discussed.

Feedback recipient

The early meta-analysis by Knaup et al. (2009) found the effect of structured feedback on treatment effectiveness was greater when both the clinician and client received feedback compared to the clinician alone. However, a subsequent meta-analysis by Shimokawa et al. (2010) reported mixed findings, with some clients not benefitting from receiving structured feedback alongside their clinician. Davidson et al. (2015) found no additional benefit in their review. It is unclear whether the recipient of continuous progress feedback influences outcomes in the context of individual therapy in psychiatric/mental health settings.

Feedback type

Intuitively, it might be assumed the addition of process feedback could improve outcomes. However, a dismantling study by Mikeal et al. (2016) found outcomes were similar when the clinician received progress only compared to progress and process feedback. This study was, however, conducted within student counselling services. The meta-analysis by de Jong et al. (2021) found studies using the PCOMS, which incorporates process feedback, had larger effect sizes (d = .24) compared to the OQ–Analyst, which provides only progress feedback (d = .13). However, this review included studies offering a range of psychological therapy formats, making it difficult to draw conclusions about feedback type in individual therapy.

Feedback plus Clinical Support Tools

Shimokawa et al. (2010) found studies which incorporated the use of CSTs improved the benefits of structured feedback for those NOT and reduced deterioration rates. However, 5/6 studies in this meta-analysis were with student samples. The recent meta-analysis by de Jong et al. (2021) did not draw any firm conclusions about the effect of CSTs.

In summary, it remains unclear whether continuous structured feedback in the context of a clinical population receiving individual psychological therapy can improve treatment effectiveness or efficiency, and whether the recipient, feedback type and incorporation of a CST influences the effects of feedback. There is also variability in clinician training and support in the implementation of structured feedback and its effects are unclear. With high demand for psychological therapy, it is important to establish whether structured feedback is effective and efficient and to maximise any potential benefits.

1.4 Aims

The aims of this review were to establish if continuous structured progress feedback within individual psychological therapy in psychiatric/mental health settings

      (1) improves treatment effectiveness, and

      (2) improves treatment efficiency

The review will also explore whether (1) feedback recipient (clinician/clinician and client), (2) feedback type (progress/progress and process), (3) CSTs (presence/not) and (4) clinician training (provided/not, and if so duration) influence treatment effect.

2. Methods

A protocol was developed in accordance with the PRISMA-P (Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols) guidelines (see checklist, Appendix 1.1, page 86) and published on the Open Science Framework (Appendix 1.2, page 89).

2.1. Search Strategy

A literature search was undertaken on 17th August 2023 in PsycINFO (Ebsco, 1600s-search date), CINAHL (Ebsco, 1981-search date), Embase (Ovid, 1947-search date) & Medline (Ovid, 1946-search date). The International Standard Randomised Controlled Trial Number Registration, The US National Institute of Health Clinical Trials and The Cochrane Central Register of Controlled Trials were searched on 18th August 2023. The search strategy is detailed in Appendix 1.3, page 90 and used a combination of Medical Subject Headings (MeSH) and keywords related to 'routine outcome monitoring' and 'structured feedback' in psychological therapy in mental health settings. All references were imported and managed in EndNote.

2.2. Eligibility Criteria

Eligible studies needed to meet all of the following inclusion criteria:

(1) Population: Adults (18+) receiving individual psychological therapy in relation to mental health and/or substance misuse difficulties

(2) Intervention: Session by session feedback on progress to the clinician, or clinician and client across the course of therapy, including presentation and interpretation of at least one PROM

(3) Comparator: Treatment as Usual (TAU), no feedback, or the availability of PROM scores but no interpretation of these

(4) Outcome: Symptom change on at least one PROM and/or total number of treatment sessions delivered prior to conclusion of a complete course of therapy

(5) Setting: Psychiatric/mental health setting that offered psychological therapy as part of public health service options

(6) Study: A comparison study (RCT, controlled trial, quasi-experimental design) published in a peer reviewed journal and written in English

Studies were excluded if they (1) involved Student Counselling Services; (2) were a meta-analysis, systematic or literature review (3) were a secondary analysis/repeated data sets.

2.3. Study Selection

Duplicate citations were removed from Endnote. Titles and abstracts were screened against inclusion criteria and ineligible papers removed. A second independent researcher screened a random sample of 5% of titles and abstracts (n = 142) for eligibility. Inter-rater reliability was substantial (Cohen's Kappa = 0.78). Discrepancies were resolved via discussion. Full texts were retrieved for remaining papers. Outcomes for full text screening were recorded in Excel. Further information was required for three papers to determine if eligible. The main author for each of these papers was contacted on two occasions to request this information. A random sample of 20% of full text papers (n = 12), with a mix of those deemed eligible and ineligible were screened for eligibility by a second independent researcher. Inter-rater reliability was perfect (Cohen's Kappa = 1). Once eligible papers were determined, their reference lists were hand searched. A UK expert in the field was consulted via email; no additional papers were identified.

2.4. Data Extraction

Data extraction of study characteristics was undertaken. Data fields were author, publication year, study location and setting, design, psychological therapies delivered, participant characteristics (sample size, age, gender, ethnicity and mental health presentation), intervention (feedback type, frequency, tool, recipient, use of warning signals, use of CST), extent of clinician training in the intervention, details of the comparator, primary and secondary outcomes, analysis and findings, including effect sizes (for whole sample and NOT if reported). Contact was made with one author, who provided information missing from a paper.

2.5. Outcomes

The two outcomes of interest were:

(1) Treatment effectiveness as measured by change on a PROM pre to post-therapy, including effect size, and where reported, the proportion of clients who made 'reliable change' as calculated by the Reliable Change Index (RCI)

(2) Treatment efficiency as measured by total number of sessions delivered to complete a full course of psychological therapy

2.6. Quality Assessment

To consider potential bias, each eligible paper was assessed using the Crowe Critical Appraisal Tool (CCAT), v1.4 (Crowe & Sheppard, 2011). This consists of eight domains, providing an overall score from 0-40, and a percentage. A higher score/percentage is indicative of better quality. A second independent researcher was provided with a random sample of 20% of eligible papers (n = 3) to undertake the same appraisal process. There was no more than a one point difference across each domain, and no more than a two point difference in total scores for each paper. Discrepancies were resolved through discussion. Consensus ratings were used for final reporting. For the purposes of this review, papers were categorised into low (80% or more), medium (70-79%) and high (total percentage up to 69%) risk of bias.

2.7. Data Synthesis

The characteristics of studies were summarised using frequencies. A narrative synthesis approach using published guidance (Popay et al., 2006) was followed. The synthesis examined (1) treatment effectiveness and (2) treatment efficiency for structured feedback versus no feedback/TAU, including a separate analysis for NOT clients if reported, (3) treatment effectiveness by feedback recipient, type, whether a CST was used and (4) extent of clinician training.

3. Results

3.1. Sample

The screening and selection process is outlined in Figure 1 (PRISMA 2020, Page et al., 2021). A total of 4490 citations were generated following the search. After removing duplicates, 2834 citations remained. Following screening of abstracts and titles, 2779 were excluded. Full texts were retrieved for the remaining 55 citations. 42 were excluded. Three papers required contact with the authors to confirm all participants received individual psychological therapy. Only one author responded and stated participants could have received group or individual therapy (Rise et al., 2012). Due to lack of clarity around the other two papers (Connolly Gibbons et al., 2015; Hansson et al., 2013) all three papers were excluded. This left 13 eligible papers. Two additional key papers were identified following hand searching of reference lists. Hence, 15 papers were eligible for inclusion.

Figure 1 – PRISMA Flow diagram (Page et al., 2021)

Identification of studies via databases and registers

Identification of studies via other methods

Identification

Records identified from: (n=4490)
  CINAHL (n=452)
  Embase (n=1271)
  PsychInfo (n=764)
  Medline (n=1037)
  Cochrane Register minus Cochrane
  Reviews (n=875)
  International RCT Reg (n=24)
  US NIH Clinical Trials (n=67)

Records removed *before screening*:

Duplicate records removed
(n=1656)

Records identified from:

Citation searching (n = 6)

Screening

Records screened
(n = 2834)

Records excluded
(n = 2779)

Reports sought for retrieval
(n = 55)

Reports not retrieved
(n = 0)

Reports sought for retrieval
(n = 6)

Reports not retrieved
(n = 0)

Reports assessed for
eligibility (n = 55)

Reports excluded (n=42)
  1. Not a Journal Article (n=3)
  2. Not an intervention study (n=7)
  3. Not FB vs No FB/TAU (n=6)
  4. FB not/unclear if in context of
  Individual PT (n=15)
  5. FB less frequent than session by
  session (n=3)
  6. FB not on PROM (n=1)
  7. Secondary Analyses (n=5)
  8. Protocol (n=1)
  9. Follow up of key paper (n=1)

Reports assessed for eligibility
(n = 6)

Reports excluded:
(n=4)
1. FB not in context of
Individual PT (n=3)
2. FB less frequent
than session by
session (n=1)

Included

Studies included in review
(n =15)
Reports of included studies
(n = 15)

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3.2 Study Characteristics

The characteristics of the studies in terms of their setting and sample are presented in Table 1.

Setting

One third of studies were conducted in the USA and just over a quarter (26.6%) in the Netherlands. Only two were conducted within the UK (13.3%). Sample sizes ranged from 2233 (Delgadillo et al., 2018) to 96 (Reese et al., 2009). Most (86.7%) were conducted within outpatient settings. Services were predominantly aimed at treating mental health difficulties (86.7%) although two studies treated those with substance misuse difficulties (Amble et al., 2015; Crits-Christoph et al., 2012). Structured feedback was implemented within a broad range of therapies, most commonly Cognitive Behavioural, Humanistic/Existential, Interpersonal and Psychodynamic psychotherapies.

Sample

All participants were recruited via a convenience sampling method. The mean age of participants ranged from M = 25.5 (SD = 7.7) to M = 42.6 (SD = 11.4). In 12/15 studies, most participants were female (63-100%). Nearly half of studies (46.7%) did not report data on participant ethnicity. UK studies reported participants were largely Caucasian and British (88-89% of sample). Studies which took place in the USA (n = 5) included participants across ethnicities. Presenting difficulties included mood, anxiety and adjustment disorders, somatoform disorder, substance misuse, eating disorders and relational problems. One study included participants with schizophrenia, although they were only 1% of the sample (Amble et al., 2015). Some studies also reported numbers of participants deemed to have a personality disorder (PD).

Table 1 –Setting & Sample Characteristics

First author (year)	Country	Sample	Setting	Age	Gender (Female %)	Ethnicity (highest %)	Mental Health Presentation (highest %)
Amble et al. (2015)	Norway	340	Psychiatric & substance misuse inpatient & outpatient clinics	*M*=35.8 (*SD*=11.6)	69%	Not reported	Affective disorder (47%) Anxiety disorder (33%)
Bovendeerd et al. (2022)	Netherlands	1733	Outpatient clinics within mental health organisations	Range *M*=37.9 (*SD*=13) - *M*=37 (*SD*=13.8)	63%	Not reported	Anxiety disorder (41.7%) Depression (29.4%) Psychosomatic (17.1%)
Brattland et al. (2018)	Norway	161	Psychiatric outpatient clinic	*M*=34.1 (*SD*=11.6)	63%	Not reported	Anxiety disorder (30.1%) Mood disorder (30.1%)
Crits-Christoph et al. (2012)	USA	304	Outpatient substance misuse clinic	Range *M*=38.8 (*SD*=11.4) – *M*=40.3 (*SD*=9.4)	44%	African American (42.4%) Caucasian (37.6%)	Problematic alcohol/drug use
de Jong et al. (2014)	Netherlands	604	Outpatient mental health care institutes/private practices	*M*=38.2 (*SD*=12)	68%	Not reported	Mood disorder (27%) (PD - 39%)
Delgadillo et al. (2017)	UK	594	Outpatient NHS mental health service	*M*=38.7 (*SD*=13.8)	63.8%	White British (87.8%)	Mixed anxiety & depressive disorder (40.2%) Depression (28.3%) Anxiety disorder (28.3%)

Study	Country	N	Setting	Age	Female	Ethnicity	Diagnosis
Delgadillo et al. (2018)	UK	2233	Outpatient NHS mental health service	M=39.2 (SD=15)	66%	White British (89%)	Mood disorder (35%) Generalised anxiety disorder (15%) Other (37%)
Errazuriz & Zilcha-Mano (2018)	Chile	547	Outpatient mental health centre	M=41.3 (SD=12.8)	74.8%	Latino (95%)	Depressive disorder (73.5%)
Hawkins et al. (2004)	USA	313	Outpatient hospital based psychotherapy clinic	M=30.8 (SD=10.5)	68%	Caucasian (94%)	Mood disorder (74%) Anxiety disorder (21%)
Janse et al. (2017)	Netherlands	1070	Outpatient mental health care organisation	M=42.6 (SD=11.4)	53%	Not reported	Adjustment disorder (26.5%) Somatoform disorder (25.9%) Mood disorder (22.5%)
Janse et al. (2020)	Netherlands	368	Outpatient mental health care organisation	M=41.4 (SD=12.2)	57.9%	Not reported	Somatoform disorder (40.2%) Mood disorder (30.2%) Anxiety disorder (22%) (PD - 34.5%)
Lutz et al. (2022)	Germany	614	Outpatient mental health clinic	M=36.3 (SD=13.7)	64.3%	Not reported	Affective disorder (50.7%) Anxiety disorder (16.2%) Adjustment disorder (12.6%) (PD - 17.1%)
Reese et al. (2009) Study 2	USA	96	Outpatient graduate training mental health clinic	M=33 (SD=12.3)	70.8%	Caucasian (79.6%) Hispanic/	Not reported

						Latino (14.6%)	
Simon et al. (2012)	USA	464	Outpatient psychotherapy clinic	M=36.1 (SD=13.3)	64%	Caucasian (92.7%) Hispanic/ Latino (2.4%)	Mood disorder (64%) Anxiety disorder (30%)
Simon et al. (2013)	USA	137	Private Inpatient Eating Disorder Clinic for women	M=25.5 (SD=7.7)	100%	Caucasian (92.5%) Asian (3%)	Bulimia (42.9%) Anorexia (31.6%) Other Eating Disorder (25.6%)

Design

The design, feedback intervention and outcomes for included studies are outlined in Table 2. Most

(80%) were naturalist RCTs. The remaining studies were quasi-experimental, involving a TAU

followed by structured feedback phase (Crits-Christoph et al., 2012; Delgadillo et al., 2017; Janse et

al., 2017). The nature of the intervention within the control/TAU group varied across studies. The

majority (80%) had participants in the TAU/Control group complete the same PROM at the same

frequency as the feedback group. In 10/12 of these studies the clinician/client did not receive any

feedback on these. In two studies, TAU involved clinicians receiving feedback in the form of graphed

scores for PROMs (Delgadillo et al., 2017; Delgadillo et al., 2018). In the remaining studies, the

control group completed a PROM on a less frequent basis, with clinicians receiving feedback on

these.

Feedback

The most common feedback system used was the OQ Analyst (46.7%), followed by the PCOMS

(33.3%). One study tested their own system, the Trier Treatment Navigator, which included

treatment recommendations (Lutz et al., 2022). Two studies did not use a formal feedback system

(Delgadillo et al., 2017; Delgadillo et al., 2018). Feedback across the studies included an up-to-date

graph of the clients' scores. Over half (60%) included an ETR on this graph. Most (80%) studies

included either a basic warning signal (5/12) or progress message (7/12) to convey detail about the

clients' progress, highlighting those who might be NOT.

Outcome Measures

Nearly half of studies used the OQ-45, with one additional study using an abbreviated version (the

OQ 30.2). Each study outlined the psychometric properties of measures used. Two thirds of studies

used the same outcome measure for feedback and outcome measurement.

Table 2 – Design, Feedback & Outcomes

First author (year)	Design	Comparator	Feedback Tool	Feedback Recipient	Feedback Details	CST	Clinician training	Primary Outcome measure	Findings Effectiveness Full Sample	Findings Effectiveness NOT Sample	Findings Efficiency Full Sample	Findings Efficiency NOT Sample
Amble et al. (2015)	RCT; Progress FB vs No FB	PROM completed every session, no FB	Norwegian OQ-45	Clinician	Graphed Scores with ETR & Progress message	N	Yes (4 hours) plus follow up	OQ-45	FB> no FB d = 0.32	FB=No FB	FB=No FB (sessions attended)	Not reported
Bovendeerd et al. (2022)	RCT; Progress & Process FB vs TAU	PROM completed pre, 2x during, and post with FB	PCOMS	Clinician	Graphed Scores & Progress signal	N	Yes (1.5 days) plus follow up	OQ-45 (Dutch) & MHC-FS (Dutch)	FB >TAU d = not reported	Not reported	FB=TAU (sessions to complete)	Not reported
Brattland et al. (2018)	RCT; Progress & Process FB vs TAU	PROM completed pre	PCOMS	Clinician	Graphed Scores	N	Yes (1 day) plus follow up	BASIS-32	FB>No FB d = 0.26	Not reported	Not reported	Not reported

		& post therapy, no FB			with ETR & Progress signal				**RCI** FB>No FB for Reliable Improvement			
Crits-Christoph et al. (2012)	Quasi-Experimental; Progress FB phase vs No FB Phase	PROM completed every session, no FB	OQ-Analyst (Modified OQ-45)	Clinician	Graphed Scores plus substance misuse responses & Progress message	Y	Yes (duration unknown)	Modified OQ-45	Not reported	FB=No FB (after CST used FB>No FB)	Not reported	FB=No FB (sessions attended)
de Jong et al. (2014)	RCT; Progress FB Clinician & Client vs Progress FB Clinician only vs No FB	PROM completed every session, no FB	Dutch OQ-45	Clinician & Client, or Clinician	Graphed Scores with line for clinical cut off &	N	Unknown	OQ-45 (Dutch)	FB Clinician & Client> FB Clinician=No FB (*rate of change)	Not reported	Not reported	Not reported

					Progress message				**RCI** FB Clinician & Client< FB Clinician (non sig trend) =No FB for Reliable Deterioration			
Delgadillo et al. (2017)	Quasi-Experimental; Progress FB phase vs TAU	PROM completed every session, scores graphed for clinician	PHQ-9 GAD-7	Clinician	Graphed Scores with ETR & Progress signal	N	Yes (6 hours)	PHQ-9 GAD-7	FB=TAU **RCI** FB=TUA for Clinically Sig Improvement & Reliable Improvement	FB=TAU	FB<TAU (sessions attended)	Not reported
Delgadillo et al. (2018)	RCT: Progress FB vs TAU	PROM completed every session,	PHQ-9 GAD-7	Clinician	Graphed Scores with ETR &	N	Yes (6.5 hours)	PHQ-9 GAD-7	FB=TAU	FB > TAU d = 0.19- 0.23	FB=TAU (sessions attended)	Not reported

		scores graphed for clinician			Progress signal				**RCI** FB=TAU for Reliable Improvement FB<TAU for Reliable Deterioration	**RCI** FB=TAU for Reliable Improvement FB<TAU for Reliable Deterioration		
Errazuriz & Zilcha-Mano (2018)	RCT: Progress & Process FB vs U Progress & Process FB vs U Process FB vs U Progress FB vs No FB	PROM & process measure completed every session. U Progress & Process FB: Clinician access to PROM & process measure; U Process FB:	Spanish OQ-30.2	Clinician	Graphed Scores & Progress message	N	No	OQ-30.2 (Spanish)	Progress & Process FB = U Progress & Process FB = U Process FB only = U Progress FB only = No FB	Progress & Process FB = U Progress & Process FB = U Process FB only = U Progress FB only = No FB	Not reported	Not reported

						N						
					Clinician access to process measure; U Progress FB: Clinician access to PROM; No FB: no access/FB							
Hawkins et al. (2004)	RCT; Progress FB Clinician & Client vs Progress FB Clinician vs TAU	PROM completed every session, no FB	OQ-45	Clinician & Client, or Clinician	Graphed Scores with line for clinical cut off & Progress message	N	Unknown	OQ-45	FB Clinician & Client> FB Clinician >TAU η² = .04 **RCI** FB Clinician & Client =TAU for Clinically Sig Improvement	FB Clinician & Client= FB Clinician=TAU **RCI** FB Clinician & Client >TAU for Clinically Sig Improvement	FB Clinician & Client= FB Clinician=TAU (sessions received)	FB Clinician & Client= FB Clinician = TAU (sessions received)

Study	Design	Measure completion	Instrument	Who	Feedback	N	Follow up	Outcome measure				
									& Reliable Improvement	& Reliable Improvement		
Janse et al. (2017)	Quasi-Experimental; Progress & Process FB phase vs TAU phase	PROM & process measure completed every session, additional PROM completed pre, every 5th session, and post, no FB	PCOMS	Clinician	Graphed Scores with ETR & Guidance on interpreting progress	N	Yes (0.5 day) plus follow up	GSI of SCL-90-R (Dutch)	FB=TAU	FB=TAU

RCI
FB=TAU for Clinically Sig Improvement & Reliable Improvement | FB<TAU (sessions attended) | FB=TAU (sessions attended) |
| Janse et al. (2020) | RCT; Progress & Process FB vs U Progress FB | PROM completed pre, every 5th session, and post with FB to clinician on scores & | PCOMS | Clinician | Graphed Scores with ETR | N | Yes (duration unknown) with follow up | GSI of SCL-90-R (Dutch) | Progress & Process FB = U Progress FB

RCI
As above for Clinically Sig Improvement | Not reported | Progress & Process FB< U Progress FB (sessions received) *d* = .22 | Not reported |

					interpretation (not graphed)				Reliable Improvement & Reliable Deterioration			
Lutz et al. (2022)	RCT; Tx Rec + Progress FB vs TAU	PROM completed every session, no FB	Trier Treatment Navigator	Clinician	Graphed Scores with dynamic ETR & Progress signal	Y	Yes (12 hours) plus follow up	Composite: HSL-11 OQ-30 QEP-2 PHQ-9 GAD-7	Tx Rec & FB =TAU	Not reported	Not reported	Not reported
Reese et al. (2009) Study 2	RCT; Progress & Process FB vs No FB	PROM completed every session, no FB	PCOMS	Clinician	Graphed Scores & Guidance on interpreting progress	N	Yes (1 hour)	ORS	FB>No FB *d* =.49 **RCI** FB>No FB for Reliable Improvement	FB=No FB	FB=No FB (sessions attended)	FB=No FB (sessions attended)
Simon et al. (2012)	RCT; Progress FB vs No FB	PROM completed every session	OQ-Analyst (OQ-45)	Clinician	Graphed Scores	Y	Unknown	OQ-45	Not reported	FB>No FB *d* =.12	Not reported	FB=No FB (sessions attended)

		and ASC if NOT, no FB			with ETR & Progress message					**RCI** FB=No FB for Clinically Sig Improvement & Reliable Improvement		
Simon et al. (2013)	RCT; Progress FB vs No FB	PROM completed every session and ASC if NOT, no FB	OQ-Analyst (OQ-45)	Clinician	Graphed Scores with ETR & Progress message	Y	Yes (2 hours) plus follow up	OQ-45	FB>No FB d = 0.3 **RCI** FB>No FB for Clinically Sig Improvement	FB>No FB d = Not reported	FB=No FB (sessions attended)	Not reported

Abbreviations: ASC: Assessment for Signal Clients; FB: Feedback; CST: Clinical Support Tool; ETR: Expected Treatment Recovery; GAD-7: General Anxiety Disorder-7; GSI: Global Severity Index; HSCL-11: Hopkins Symptom Checklist-Short Form-11; MHC-SF: Mental Health Continuum-Short Form; N: No; NOT: Client 'Not on Track'; ORS: Outcome Rating Scale; OT: Client 'On Track'; OQ: Outcome Questionnaire; PCOMS: Partners for Change Outcome Management System; PHQ-9: Patient Health Questionnaire-9; PROM: Patient Reported Outcome Measure; QEP-2; Questionnaire for the Evaluation of Psychotherapeutic Progress-2; RCT: Randomised Controlled Trial; RCI: Reliable Change Index; SCL-90-R:Symptom Checklist 90-Revised; Sig: Significant; TAU: Treatment as Usual; Tx Rec: Treatment recommendations; U: Unstructured; Y: Yes

Risk of Bias (see Section 3.3):

Low	Medium	High

3.3. Assessment of Bias and Quality

Table 3 outlines ratings for each paper on the CCAT. Total percentage ratings ranged from 60% (Simon et al., 2012), a high risk of a bias, to 80% (Bovendeerd et al., 2022; Delgadillo et al., 2018), a low risk of bias. Eleven studies were deemed to have a moderate risk of bias.

Strengths of the papers were that valid and reliable outcome measures were used. Most studies incorporated validated feedback systems, with manuals/resources provided to clinicians to support implementation. Studies took place in naturalistic settings, providing high ecological validity and good generalisability.

However, there were limitations with regards to design. The clinician, client and the often researcher were not blind to the group allocation of the client, with potential for expectancy effects and demand characteristics. Where clients completed measures with no feedback, it is possible these participants gauged their progress through this activity and shared this in some way with clinicians, or that this process had a detrimental effect for clients, both of which could have impacted on findings. Rarely were any effective adherence or fidelity checks used to assess the implementation of structured feedback and there was no monitoring of other mental health treatments (e.g. medication). Lastly, it was difficult to tease out the role that training and implementation support had on outcomes.

Bias in sampling was common. Clinician's often volunteered to participate and clinicians frequently were responsible for recruiting clients. Most studies had no power calculation. Ethical subjectivities were rarely commented on, despite some researchers also being clinicians and the developers of feedback systems.

Studies with a high risk of bias were found to have more of the issues above, rather than inherent differences. Those with low risk of bias had either published a protocol or registered their research, conducted an a priori sample size calculation and had large sample sizes.

Table 3: Quality Appraisal

Study	Preliminaries	Introduction	Design	Sampling	Data collection	Ethical	Results	Discussion	Total	Total %
Amble et al. (2015)	4	4	3	3	4	3	4	4	29	72.5%
Bovendeerd et al. (2022)	3	5	3	5	4	5	4	3	32	80%
Brattland et al. (2018)	4	5	3	3	3	3	4	3	28	70%
Crits-Christoph et al. (2012)	4	5	2	4	4	4	4	3	30	75%
de Jong et al. (2014)	4	5	3	3	3	3	4	3	28	70%
Delgadillo et al. (2017)	4	4	2	3	3	4	4	5	29	72.5%
Delgadillo et al. (2018)	4	4	4	4	3	4	4	5	32	80%
Errazuriz & Zilcha-Mano (2018)	4	5	3	4	3	4	4	4	31	77.5%
Hawkins et al. (2004)	4	5	3	3	3	3	3	5	29	72.5%
Janse et al. (2017)	3	5	2	3	3	3	4	5	28	70%
Janse et al. (2020)	4	4	3	4	4	4	4	4	31	77.5%
Lutz et al. (2022)	3	5	3	4	3	4	4	4	30	75%
Reese et al. (2009) Study 2	3	5	2	2	4	2	4	3	25	62.5%
Simon et al. (2012)	3	3	3	3	3	3	3	3	24	60%
Simon et al. (2013)	4	4	4	3	4	4	3	5	31	77.5%

3.4 Treatment Effectiveness

Effectiveness was tested using multiple regression techniques (73.3% of studies) or an ANCOVA, with pre-therapy PROM score as a covariate. Thirteen studies (86.7%) analysed the change in PROM scores pre to post-therapy for structured feedback versus a control group/TAU for all participants in the study. Of these, half (n=6) found structured feedback was effective, with a small effect size ranging from d = .26 (Brattland et al., 2018) to d = .49 (Reese et al., 2009). De Jong et al. (2014) looked at rate of change in symptomology instead and found progress feedback to the clinician and client to be associated with significantly faster changes compared to no feedback. The remaining studies (n=6) reported no effect of structured feedback.

Changes based on the RCI were tested for statistical difference in eight studies. Three studies found a significantly greater odds of clinically significant/reliable improvement, or significantly lower odds of reliable deterioration for clients receiving structured feedback. Four studies found no significant difference and one reported mixed findings (Delgadillo et al., 2018).

The quality and characteristics of studies that found a significant effect of structured feedback for the whole sample (n=6) were compared to those that did not (n=6). Whilst a study deemed to be at highest risk of bias found a positive effect of feedback (Reese et al., 2009), a study rated the lowest risk of bias also demonstrated a positive effect (Bovendeerd et al., 2022). The average quality rating for studies that found no effect (75.4%) was similar to that of studies that did find an effect (72.5%). Studies that found a significant effect of feedback were all RCTs, whereas 2/5 of the studies which found no effect were quasi-experimental. All studies demonstrating effectiveness used either the OQ-Analyst or PCOMS, whereas 2/5 studies which showed no effect did not. Most of the studies that found an effect of feedback (4/6) involved a comparator that completed weekly PROMS with no feedback. This contrasts with studies where no effect was found, where 2/5 studies had clinicians receive some form of unstructured feedback. There did not appear to be any patterns with regards to studies that did and did not use the same tool for feedback and outcome measurement. In summary, the characteristics of the studies, such as the comparator and feedback system used may be influential in findings.

Treatment Effectiveness for 'Not On Track' Participants

Twelve studies reported the proportion of participants in the sample that met criteria for NOT, ranging from 14-20% (de Jong et al., 2014) to 58% (Delgadillo et al. 2018). However, de Jong et al. classified participants as NOT after two episodes where scores indicated deterioration, unlike other studies which based this on one episode.

Two thirds of the studies tested the effect of structured feedback on improvement in symptomatology in the NOT sample. Only 3/10 studies showed a significant effect of feedback, with small effect sizes ranging from d = .12 (Simon et al. 2012), a study deemed to be at high risk of bias, to d = .23 (Delgadillo et al., (2018), a study deemed to be at low risk of bias. These effect sizes are smaller than those found for the full sample. One additional study demonstrated a significant effect of feedback on symptom change after clients were identified as NOT and a CST was utilised (Crits-Christoph et al., 2012).

Findings were mixed in the four studies where the RCI was reported. Two studies found no significant differences (Janse et al., 2017; Simon et al., 2012), one study found significantly greater proportions of Clinically Significant Improvement & Reliable Improvement in the feedback group (Hawkins et al., 2004) and one study reported mixed findings (Delgadillo et al., 2018). Support for structured feedback for those NOT therefore appears weaker than for the whole sample.

3.5 Treatment Efficiency

Nine studies (60%) examined whether there were differences across the full sample in sessions attended/received for clients participating in the feedback intervention versus TAU/no feedback. One third (n=3) found structured feedback significantly reduced the number of sessions attended/received (Delgadillo et al., 2017; Janse et al., 2017; Janse et al., 2020), with a small effect size, d = .22 (Janse et al., 2017). Interestingly, these three studies found no effect of feedback on treatment effectiveness. In two of these studies, the clinicians in the control group received feedback on PROMs, but less frequently. None of the studies incorporated a CST. When looking at the NOT sample, no studies found an effect (n=5). Only one study examined treatment effectiveness in terms of how many sessions were attended for completion of a course of therapy (Bovendeerd et al., 2022) and no studies looked at attendance separately for OT and NOT samples. Given these limitations, potential mediators of the effect of feedback will be looked at for treatment effectiveness only.

3.6 Feedback Type

Half of studies (n=3) which provided progress only feedback (one of which involved feedback to the clinician and client), and half of studies which provided progress and process feedback (n=3) found a significant effect of feedback on changes in symptomatology. For clients deemed NOT, all three studies that found an effect of structured feedback used progress feedback only. One study directly compared progress and process feedback with progress feedback (Errazuriz & Zilcha-Mano, 2018) and found no differences, although progress feedback alone was unprocessed. There is a lack of research on whether the addition of process feedback can improve treatment effectiveness.

3.7 Feedback Recipient

Most of the studies (86.7%) provided feedback solely to the clinician. However, 12/13 of these studies explicitly stated the clinician was encouraged to share feedback with clients. Making comparisons by recipient is therefore difficult as it is unknown how many clients received informal progress feedback within therapy sessions. Where studies demonstrated an effect of feedback, 5/6 studies involved feedback solely to the clinician for the whole sample, and 3/3 studies for the NOT sample. Two studies directly compared outcomes of feedback to clinician only versus clinician and client (de Jong et al., 2014; Hawkins et al., 2004) and concluded feedback to the clinician and client was superior. These findings suggest structured feedback to the clinician can be effective, but feedback explicitly to the client might enhance its effects.

3.8 Clinical Support Tools

Only four studies used a CST as part of the feedback intervention; the 'Assessment for Signal Clients', ASC (Lambert et al., 2007). In three studies, the ASC was administered when the client was identified as NOT, and in one study at routine points during therapy (Lutz et al., 2022). Two studies using a CST found structured feedback to be effective for the NOT sample. One of these studies was deemed to have a high risk of bias (Simon et al., 2012), but the other study was of better quality (Simon et al., 2013). One additional study demonstrated an effect of structured feedback for NOT only once a CST had been implemented (Crits-Christoph et al., 2012) and the remaining study, which administered the CST routinely, found no effect of structured feedback on the full sample, but did not report results for NOT separately (Lutz et al., 2022). These findings suggests CSTs may be important for improving the effectiveness of feedback for those NOT.

3.9 Clinician training

Eleven studies (73%) stated clinicians were trained in the feedback intervention. One study purposefully did not train clinicians (Errazuriz & Zilcha-Mano, 2018). The amount of clinician training varied, ranging from one hour (Reese et al., 2009) to 12 hours (Lutz et al., 2022). The average hours reported was six hours. Seven of the eleven studies that delivered staff training incorporated follow up; additional training workshops, meetings, supervision and/or consultation. Patterns of staff training were similar across studies that found and did not find an effect of structured feedback, for both whole and NOT samples. It is therefore unclear as to the role of staff training in effectiveness of structured feedback.

4. Discussion

4.1 Overview of Findings

This review examined whether continuous structured feedback can lead to improvements in the effectiveness and efficiency of individual psychological therapy in psychiatric/mental health settings, and whether these outcomes are influenced by feedback characteristics.

The review found that structured feedback in individual psychological therapy has been tested across a variety of psychiatric settings, client presentations and psychological therapies.

The results are inconclusive as to whether structured feedback can improve effectiveness in individual psychological therapy with clinical populations. This fits with a previous review by Gondek et al. (2016) who found 56% of included studies showed a positive effect of structured feedback on treatment effectiveness in mental health interventions. This review does highlight that the complexity of client presentations may not be a significant a factor in whether structured feedback is effective, given that Gondek et al.'s review included University Counselling Services. The design of studies appears to have played a role in whether an effect of structured feedback was found (e.g. RCTs, using a structured feedback tool, with a no feedback comparator). This raises the possibility that structured feedback may be more effective when delivered as part of an existing feedback system, but this comes with additional implementation costs.

There was limited evidence to suggest structured feedback was more effective for those NOT versus the whole sample. This is contrary to a previous review of feedback in individual psychological therapy (Davidson et al., 2014). However, Davidson's review included a large number of studies which took place in university settings. There was some evidence to suggest that structured feedback may bring about greater changes for a client once they have been identified as NOT (Crits-Christoph et al., 2012) and this requires further research.

Only one study in this review directly tested if process and progress feedback was superior to progress only feedback. More research is needed in this area. With regards to recipient, this review suggests the addition of client feedback may enhance treatment effectiveness. Knaup et al. (2006) reported similar findings. There were only a limited number of studies which included a CST as part of structured feedback. This review indicates CSTs might be beneficial

for clients once they are identified as NOT. A recent meta-analysis by de Jong et al. (2022) did not find CSTs to be a significant moderator of the effects of feedback. However, this review included all forms of psychological therapy delivery. Perhaps CSTs are more effective when delivered within individual therapy, providing personalised pathways to help the client reduce the discrepancy between their actual and desired goal state. It was unclear from this review what the role of clinician training and support might be in structured feedback. Studies have found therapist factors can moderate the effect of structured feedback (de Jong et al., 2012). Training and support to implement structured feedback will have a role in shaping these factors.

The review was unable to draw any conclusions regarding the impact of structured feedback on the efficiency of individual psychological therapy. There were no studies that compared efficiency separately for OT and NOT, and only one study that measured efficiency by sessions required to complete therapy rather than numbers attended/received.

4.2 Strengths & Limitations

This is the first review to examine the effectiveness and efficiency of structured feedback specifically within individual therapy in mental health/psychiatric settings. Studies were undertaken in a range of settings, meaning high ecological validity and generalisability. This review has the potential to be of value for public funded services such as the NHS where there are continuous efforts to improve effectiveness and efficiency.

Limitations are that the review only included peer reviewed, English language journal articles, meaning there was a risk of publication bias. Two papers were excluded due to lack of clarity around the context in which structured feedback took place. It is unknown whether their inclusion would have changed the findings of this review. Studies varied in psychological interventions, feedback characteristics and comparators, which made synthesis of data more difficult. Variations in the presentation of feedback (e.g. presence of ETR curve or progress message) were evident but exploration of this was not an aim of this review. There were few studies conducted within the UK, limiting the applicability of conclusions to the NHS.

4.3 Further Research

More high quality research into the effectiveness of structured feedback in the context of individual psychological therapy in public funded mental health settings is required, including in the UK. Standardisation of outcome measures would allow a future meta-analysis. To test more robustly treatment efficiency, studies should report the number of sessions received to complete therapy, and do this separately for OT and NOT. Exploration around the role of clinician training and implementation support, and the use of CSTs, particularly after clients have been identified as NOT, are needed. Exploring further clients' experiences of receiving feedback on PROMs, as well completing but not receiving feedback would be enlightening.

5. Conclusion

Structured feedback when provided continuously can improve the effectiveness of individual therapy with clients with more severe presentations and therefore should not be ruled out for this population. However, thought needs to be given to what feedback tools are used and how feedback is implemented. The incorporation of explicit client feedback and a Clinical Support Tool should be considered. More robust research is needed on when, for who, and in what way structured feedback is most helpful.

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Chapter 2

Using a Goal Based Outcomes approach in an Older Adult Psychology Service: Goal types generated, their attainment and how they are categorised by clinicians

Prepared in accordance with the author requirements for Aging and Mental Health

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Plain Language Summary

Types of goals older adults set when attending psychology services, their attainment, and whether clinicians categorise them the same way.

Background

It is important that psychology services measure if input is helpful. Often questionnaires are used, but these focus on symptoms. The Goal Based Outcome (GBO) approach (Law, 2011) asks clients to state their goals for input and rate how well they are meeting these before and after.

Aims & Questions

This study explored the use of a GBOs approach in an Older Adult Psychology Service (OAPS).

The research questions were:

1. What types of goals do older adults set in an OAPS?
2. Do clients' scores on a symptom questionnaire at the end of their input correlate with their average goal attainment?
3. Does goal type play a role in goal attainment?
4. Can staff working within OAPSs categorise goals in the same way?

Method

In the first phase of the study, participants were older adults who generated GBOs whilst attending an NHS Scotland OAPS within a two year time period. Basic demographic information, goals set, clients' rating from 1-10 of how well these were attained, and scores on a symptom measure at the end of input were collected as part of usual practice. GBOs were put into categories using two different goal categorisation tools, then counted and described. Where available, clients' scores on their symptom questionnaire were compared with their average goal attainment to see if they correlated. Scores on goal attainment were also compared by different goal types.

In the second phase of the study, participants were clinicians working within different NHS Scotland OAPSs. They were invited via email to take part in an online task categorising a

sample of 25 goals. Basic demographic information was gathered. Level of agreement was calculated for the goal categorisation responses.

Main Findings & Conclusions

Older adults were most likely to set goals around managing symptoms and doing more activities. This is different to the patterns of goals set in research with adults and young people. Older adults may have different needs. The correlation between symptoms scores and goal attainment was low. This has been found with other client groups. This suggests GBOs measure changes not captured by questionnaires. OAPSs might wish to consider the use of GBOs.

When clients set goals that were consistently approach-orientated (seeking out desired outcomes rather than trying to reduce unpleasant outcomes) they had higher attainment scores. Clinicians could consider this when agreeing goals with clients. The overall level of agreement across clinicians when categorising the sample goals was low. However, agreement did vary by goal, with some goals having 100% agreement. Agreement appeared to be influenced by the way the goals were stated. The study highlights areas that would need to be addressed before GBOs could be grouped together to show outcomes at a service level.

References
Law, D. (2011). Goals and Goal Based Outcomes (GBOs): Some Useful Information. (2nd ed.) London: CAMHS Press

Abstract

Objective: To establish the types of goals older adults generate, their attainment and whether they can be categorised reliably by clinicians in Older Adult Psychology Services (OAPSs).

Method: This was an observational study. 313 goal units set by 122 clients were categorised into goal type and orientation and described. Differences in goal attainment by goal type and orientation were explored (n=59). Correlation analysis tested the strength of the relationship between goal attainment and scores on the Hospital Anxiety & Depression Scale, HADS (n=49). Thirty two clinicians categorised a sample of 25 goal units by type and orientation.

Results: Coping with Problems and Symptoms was the most common goal type set. A weak correlation, r = -.28, was found between both goal attainment and HADS Anxiety (p = .055) and goal attainment and HADS Depression (p = .049). Goal attainment was higher for clients who set exclusively approach-orientated goals (p = .005). Clinician inter-rater reliability was moderate for goal type (Light's Kappa = .48) and fair for goal orientation (Light's Kappa =.32).

Conclusions: The results demonstrate the potential value of a Goal Based Outcomes approach in OAPSs, and learning points for those who wish to collate this data at a service level.

1. Introduction

1.1 Outcome Measurement

Measuring and tracking outcomes in psychological services may increase therapeutic effectiveness (de Jong et al., 2021), support clinician skill development (Whipple & Lambert, 2011) and drive service improvement (Wolpert et al., 2012). Gauging the impact of psychological interventions by measuring only symptom change can overlook progress that might occur in other areas important for clients, like increased understanding, acceptance or a sense of coping (Jacob et al., 2017). Idiographic approaches aim to appraise these (Sales et al., 2022).

Idiographic measures can be problem or goal-focussed (Lloyd et al., 2018). Supporters of the approach state it brings a focus to the intervention (Renger & Macaskill, 2021), captures what is most meaningful to the client (Jacob et al., 2018), facilitates 'goal consensus' between client and clinician (Sales et al., 2019), optimises treatment planning (Antunes et al., 2020), and improves retention in therapy (Jacob et al., 2020). It is also argued idiographic approaches encourage the setting of approach-orientated goals; those focussed on desirable, positive outcomes (Jacob et al., 2018). Idiographic measures therefore support both the contracting of goals and measurement of change (Jacob et al., 2016).

An idiographic approach is particularly appealing for services where changes in symptomatology may not be the sole focus, such as Older Adult Psychology Services (OAPSs). Older adults are more likely than younger adults to experience long-term health conditions, sensory impairments, poor sleep, grief and loss, and cognitive difficulties (Woods, 2008). Having methods that measure change more broadly than the presence and intensity of symptoms may be useful.   One goal-focussed idiographic measure used with older adults is Goal Attainment Scaling (Kiresuk et al., 1994). This tool asks clients to specify their goals for intervention and expected levels of progress, with clear indicators as to whether this progress is either met, not met or exceeded, rating this on a five point scale. It has been used in a range of older adult services, including physical rehabilitation (Waldersen et al., 2017), Day Hospital (Stolee et al., 2012) and Care Home settings (Gordon et al., 1999). The use of this measure is limited, however, as clinicians require formal training in administration and completion time is lengthier than

other measures (Lloyd et al., 2018). One alternative and more simplistic measure is the Goal Based Outcome (GBO) tool (Law & Jacob, 2015). Clients are invited to generate up to three goals for their intervention and rate their success on achieving these from 0-10 at a minimum of the start and end of therapy. This approach has largely been used in Child & Adolescent Mental Health Services (CAMHS) within the National Health Service (NHS) in the UK but is designed to be compatible with any evidence-based intervention (Law & Jacob, 2015). Exploring its use with older adults is indicated.

1.2 Goal Types

A GBOs approach also informs services about the types of goals and expectations clients have. In an adult psychotherapy sample, goals were found to belong to five key types; Coping with Problems and Symptoms, Interpersonal goals, Wellbeing and Functioning, Existential Issues and Personal Growth (Berking et al., 2005). These goal types are similar to those identified in a content analysis of GBOs set in a CAMHS setting, with the exception of existential issues (Bradley et al., 2013).

Goal types may vary dependent on the service clients attend. Rupani et al. (2014) used the same goal taxonomy tool developed by Berking et al. to categorise goals young people set in a school-based counselling service and reported having to adapt the tool, retaining only Interpersonal and Personal Growth type goals. Smith et al. (2023) identified an additional theme around behavioural management/cooperation for goals set by young people in a Children's Wellbeing Practitioner service, and GBOs set within digital therapies have found different themes (Banwell et al., 2023).

There is limited research characterising the goals older adults generate when presenting to psychological services. Goals types might be different. Clients are more likely to be at a later life stage (Erikson, 1985) and having to adapt to ageing (Schaie and Willis, 2000). This requires exploration.

1.3 Goal Attainment and Symptomatology

As symptom reduction is only one type of client generated goal, proponents of the GBO approach state idiographic measures gauge changes not captured by Patient Reported Outcome Measures, PROMs (Edbrooke-Childs et al., 2015). Smith et al. (2023) found a weak but significant negative correlation (-.16 to -.22) between subscales of a PROM and GBO change scores for young people attending psychological therapy, whilst Wolpert et al. (2012) found a non-significant correlation with a similar population. It is unclear if these findings extend to other populations such as older adults, and whether GBOs have a role in capturing change in OAPSs.

1.4 Goal Attainment by Goal Type/Orientation

Older adult research is also needed to examine goal attainment in psychological therapy, as the types of goals clients generate may influence their accomplishment. Berking et al. (2005) found clients who set goals around Wellbeing and Functioning in therapy were significantly more likely to attain these than those who set goals related to Existential Issues. However, the difference was small (η^2 = .01) and reduced further when accounting for client motivation and severity of difficulties (η^2 = .007). In contrast, Rupani et al. (2014) found no influence of goal type on attainment.

The orientation of goals may also be important. In a student counselling service, those who set approach-orientated goals were found to have higher goal attainment and healthier psychological wellbeing post-therapy compared to those who set avoidance-orientated goals (Elliot & Church, 2002). This finding was not replicated, however, in an inpatient setting with clients experiencing depression where goal attainment was comparable across approach and avoidant-orientated goals (Wollburg & Braukhaus, 2010). Negotiating goals is a key part of the therapeutic process (McLeod & MacKrill, 2018). Knowing if certain goal types and orientations are more reliably attained has clinical value.

1.5 Goal Type Agreement

Finally, for goal types to inform treatment planning, and be aggregated to measure change across a service, clinicians would need to be able to categorise and group goals in a reliable way. Berking et al. (2005) found high agreement between two raters (Cohen's Kappa = .83) using the Bern Inventory to categorise goal type, and Rupani et al. (2014) found substantial levels of agreement (Fleiss Kappa = .69) between three raters using an adapted version of the Bern Inventory. Whether goals can be categorised reliably across multiple raters, as would be required in routine clinical practice, has yet to be tested.

1.6 Summary

Little is known about the types of goals generated by clients in OAPSs. Research with other populations suggests GBOs measure changes not captured by nomothetic measures. It is unclear if this applies to an older adult population. Whether the type and orientation of goals influence attainment has not been explored in older adults. It is unknown if multiple clinicians in routine practice can categorise reliably goals set by clients.

1.7 Aims

This study aims to (1) categorise and describe the types of goals older adults generate when using a GBO tool in an OAPS (2) test if goal attainment ratings correlate with symptomatology post-intervention (3) explore whether types of goals set differ significantly in their attainment and (4) investigate whether clinicians can reliably categorise goals into type and orientation.

It was hypothesised there would be (1) a weak, non-significant correlation between goal attainment & symptomatology (2) a significant difference in attainment across goal type and orientation and (3) that clinicians could reliably categorise goals by type. Categorisation by orientation was exploratory.

2. Methods

This was an observational study consisting of two phases. Phase one involved the analysis of outcome data, including GBOs, collected within an OAPS. In phase two, clinicians across a number of OAPSs undertook a goal categorisation task using a sample of phase one GBO data. A protocol for the study was published on Open Science Framework (Appendix 2.6, page 110). This research is reported in line with APA standards (Appendix 2.7, page 111).

2.1 Setting

Phase one took place in an OAPS in NHS Ayrshire & Arran, Scotland. This health board serves a population of 366,110, with 32% of the population over aged 60 and 11.4% aged 75 or over (National Records of Scotland, 2018). The area wide service is needs rather than age led, accepting referrals for those with co-morbid age-related functional and organic issues from community, inpatient and acute settings. Phase two of the study involved clinicians from OAPSs across NHS Scotland.

2.2 Ethics

The study was approved by East of Scotland NHS Research Ethics Service (Appendix 2.2-2.4, page 97-105) and authorised by Research & Development in the hosting health board (Appendix 2.5, page 107). Participant Identification Centres (PIC) agreements were granted by health boards where clinicians were recruited from.

2.3 Participants

In Phase one, participants were clients who attended and recorded outcome measures as part of routine clinical practice in NHS Ayrshire & Arran's OAPS. In phase two, participants were clinicians working in OAPSs across eight Scottish health boards. A convenience sampling approach was used where clinicians were invited via email to participate in an anonymous

goal categorisation task, with an invitation email sent to each of the service leads for distribution.

2.4 Instruments

GBO Tool: The GBO tool (Law & Jacob, 2015) was completed by clients of NHS Ayrshire & Arran's OAPS, with support from their clinician. Clients were asked to generate up to three goals for their intervention and rate their success on achieving these using a Likert scale from 1 (not attained at all) to 10 (fully attained) pre and post-intervention. A key strength of this measure is its clinical utility.

Hospital Anxiety and Depression Scale, HADS: Clients were also asked to complete the 14 item HADS (Zigmond & Snaith, 1983) pre and post-intervention. This measure provides an overall score for symptoms of depression and anxiety which indicates both case-ness and severity of symptoms. A total score can also be calculated. The HADS has sound psychometric properties for use as an outcome measure with older adults (Djukanovic et al., 2017).

Bern Inventory (Version 4.0): The Bern Inventory is a goal taxonomy tool, based on goals generated by adults in psychological therapy. The tool is deemed reliable and valid for research and practical use (grosse Holtforthe & Grawe, 2002). The taxonomy consists of five goal types; Coping with problems and symptoms, Interpersonal goals, Wellbeing and functioning, Existential issues and Personal growth. Within these five overarching goal types are 28 goal categories and 54 sub-categories, as well as categories for items that are unknown or not specified. Hence, any goal can be categorised at the type, category and sub-category level. The tool has not been tested specifically with older adults.

Working definitions of approach and avoidance-orientated goals: Working definitions informed by the literature (Elliot & Church, 2002) were developed to enable categorisation of goal units as either approach, avoidant or unclear (Appendix 2.8, page 115).

2.5 Procedure – Phase One

Clinicians within NHS Ayrshire & Arran's OAPS administered and recorded the outcomes from the GBO tool and HADS pre and post-intervention as part of routine clinical practice for clients seen for individual psychological intervention. The goals set, their attainment score and HADS scores were entered into a record keeping system, from which this data could be extracted. The Field Supervisor discovered a system issue with capturing pre-intervention goal attainment scores. A decision was made to analyse post-intervention data only. The author, who was the Principal Investigator (PI), was granted access to an anonymised database incorporating post-intervention outcome data as well as the clients' age and gender, covering a two-year period (beginning April 2021-end April 2023).

2.6 Analysis – Phase One

Goal Type

Each goal expressed by a client was broken down by the PI into goal units (specific individual goals) using the same process undertaken by gross Holtforth & Grawe (2002). Each goal unit was then categorised by the PI into goal type, category and sub-category as per the Bern Inventory, and orientation as per the working definitions. An example of this process is detailed in Figure 1.

Figure 1: Process for Categorising Goal Based Outcomes
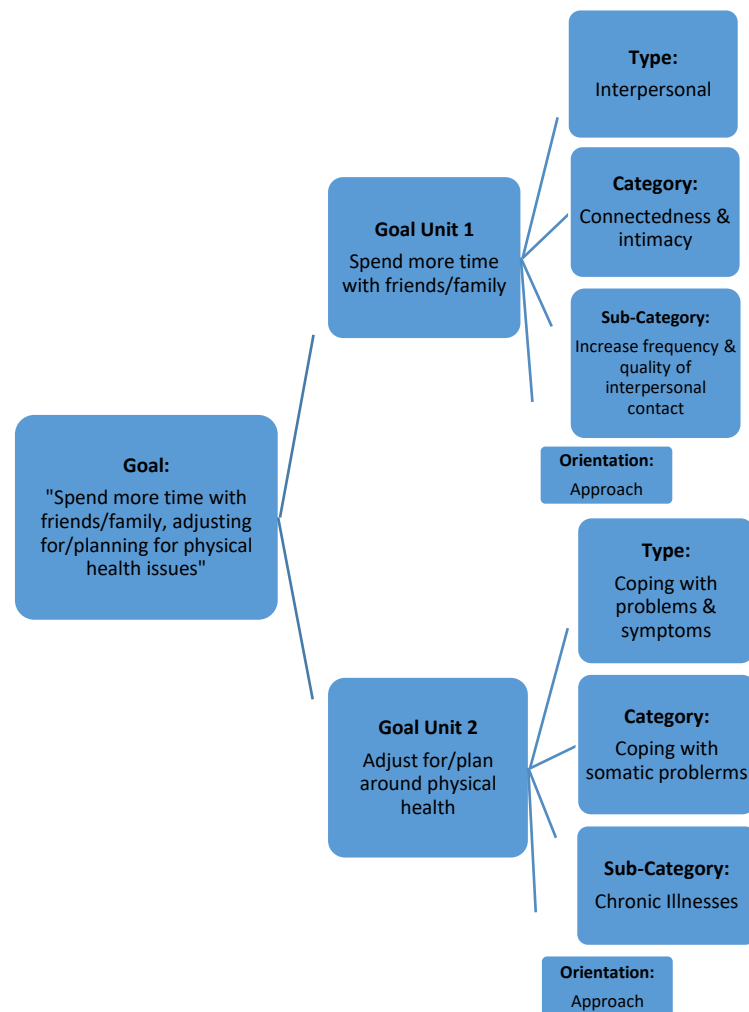
Goal categorisation was an iterative process. With permission of prof. grosse Holtforth, additions to the Bern Inventory at the category and sub-category level were discussed and agreed within the research team (PI, Field & Academic Supervisor) in order to accommodate distinct goals generated by clients of the OAPS. Three categories and 11 sub-categories were added (see Appendix 2.9, page 116). When the adapted Inventory was finalised, the goal units were categorised for the final time. A randomly selected sample of goal units (10%) was categorised by a second rater using the adapted inventory. There was substantial level of agreement at the goal type level (Cohen's Kappa = .77). Discrepancies were resolved via discussion. The frequency of each goal unit at the type, category and sub-category level was then calculated, along with orientation.

Goal Attainment

An average post-intervention goal attainment score was calculated for each client where available. To test the correlation between clients' average goal attainment and symptomatology (HADS Anxiety, HADS Depression and HADS Total score) post-intervention three bivariate correlations were conducted. A power calculation indicated a minimum of 113 clients would be required to find a weak correlation (0.3) using a two-tailed test.

Goal Attainment by Goal Type/Orientation

Clients could generate more than one goal unit per goal type. To examine if goal attainment post-intervention differed by goal type, the average goal attainment rating for each goal type per client was calculated. This process is illustrated in Figure 2.

Figure 2: Process for Calculating Goal Attainment by Goal Type & Orientation
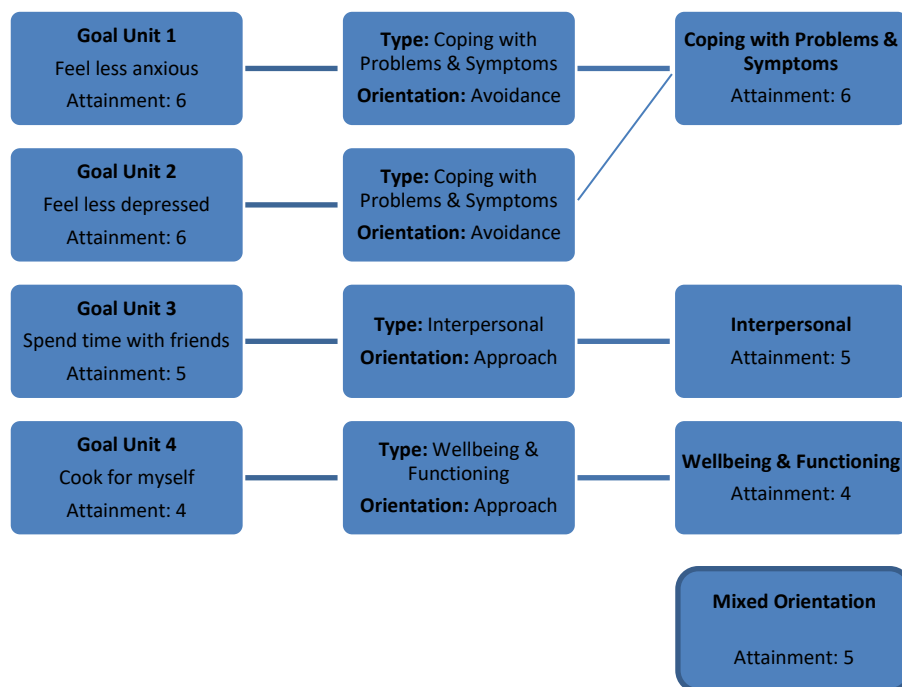
The planned protocol was to conduct a regression analysis, examining if goal type and orientation were predictors of goal attainment. There was insufficient data to meaningfully undertake this analysis. Attainment by goal type is described. Clients were grouped into those that set exclusively approach, avoidance or unclear goals, or mixed goals (if they set more than one type of goal orientation). A one-way between-groups analysis of variance was undertaken to test differences in attainment by goal orientation. As there was minimal

evidence on the magnitude of effect goal type or orientation might have on goal attainment, sample size was determined by the data available.

2.7 Procedure – Phase Two

A goal categorisation task was developed in an online survey package, Qualtrics. Clinicians were provided with a link to this task should they wish to participate. Clinicians were presented with 25 randomly selected goal units from all the goal units recorded in phase 1. Clinicians were asked to categorise each goal unit into goal type, as per the adapted Bern Inventory (five types plus unknown) and orientation (approach, avoidant or unclear). They were provided with the adapted Bern Inventory and the working definitions for orientation to support them. The task was available for completion between 19/09/23 to 17/11/23. Further information on the materials that were embedded into the online task can be found in Appendix 2.10-2.13, page 120-123. Participants were unable to proceed with the task until they indicated their consent.

2.8 Analysis - Phase Two

Inter-rater reliability between clinicians for both goal type and orientation was examined using Light's Kappa. There was minimal research on the level of agreement for more than three raters categorising goals. Sample size was therefore determined by those who agreed to participate, with the aim of recruiting 30 clinicians.

3. Results

3.1 Service Activity

Based on 2022 figures, the OAPS received on average 17 referrals per month, 77% of which were accepted (155 referrals per year). Most referrals were for individual therapy or neuropsychological assessment (71%). GBOs were recorded as part of 122 episodes of care. Clients' mean age was 71.6 years (SD = 6.4), with a range from 53-88 years. Sixty three percent of clients were female.

3.2 Goal Types

A total of 239 GBOs were generated by clients at the outset of therapy, with a further five set during the therapy process (n = 244). The majority of clients (50%) set two GBOs. When GBOs were categorised into goal units, this resulted in 313 goal units. Most participants set between 2 (35%) and 3 (33%) goal units.

Table 1 summarises the type, category, and sub-category of each goal unit as per the adapted Bern Inventory. The most frequent goal type generated was Coping with Problems and Symptoms (52.1%) followed by goals related to Wellbeing and Functioning (21.7%). Existential goals (2.6%) were least common. Only a small number of goal units (n=3) were categorised as Unknown, suggesting the adapted tool was acceptable.
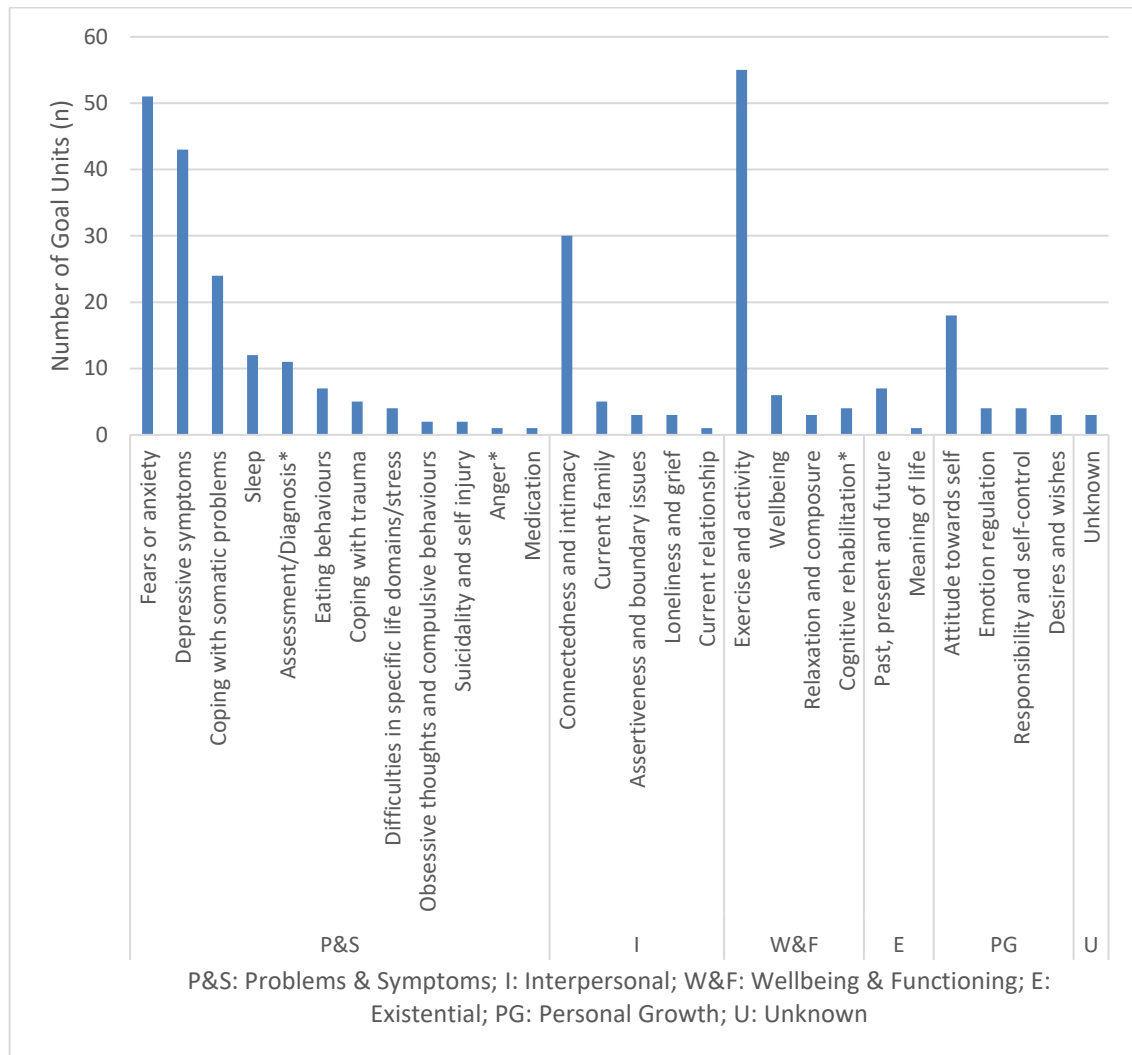
Table 1: Frequency of Goal Units by Type, Category and Sub-Category

Goal Type & Category (n)	Goal Sub-Category (n)
1. Coping with Problems & Symptoms (n=163)	
Depressive symptoms (n=43)	Negative thoughts (n=2), Negative moods (n=30), Loss of drive/energy (n=11)
Suicidality & self-injury (n=2)	Self-injurious behaviour (n=1), Suicidality (n=1)
Fears or anxiety (n=51)	Fears/anxiety in specific situations (n=15)
	Fears/anxiety in specific situations - fear of falling* (n=3)
	Panic attacks (n=3)
	Social phobic fears (n=4)
	General anxiety* (n=21)
	Physical symptoms* (n=3)
	NOS (n=2)
Obsessive thoughts/compulsions (n=2)	Obsessions and compulsions (n=2)
Coping with trauma (n=5)	Traumas (n=5)
Eating behaviours (n=7)	Coping with problematic eating behaviours (n=2), Obesity (n=4), NOS (n=1)
Sleep (n=12)	Sleeping problems (n=12)
Coping with somatic problems (n=24)	Pain (n=4), Chronic illnesses (n=14), Anxiety around persistent physical symptoms* (n=1), NOS (n=5)
Difficulties in specific life domains/stress (n=4)	Stress (n=3), Time management (n=1)
Anger* (n=1)	Anger* (n=1)
Assessment/Diagnosis* (n=11)	Assessment - Neuropsychological* (n=9)
	Assessment - Mental health* (n=1), NOS (n=1)
Medication (n=1)	Medication (n=1)
2. Interpersonal Problems (n=42)	
Current relationship (n=1)	Relationship with partner (n=1)
Current family (n=5)	Parenthood (n=2), Family situation (n=3)
Loneliness and grief (n=3)	Grieving loss (n=3)
Assertiveness and boundary issues (n=3)	Assertive behaviours (n=3)
Connectedness and intimacy (n=30)	Increase frequency and quality of interpersonal contact (n=28), Permitting intimacy (n=2)
3. Wellbeing & Functioning (n=68)	
Exercise and activity (n=55)	Increase exercise (n=12)
	Improve mobility* (n=2)
	Improve leisure activities (n=27)
	Increase engagement in ADLs* (n=14)
Relaxation and composure (n=3)	Learn to relax (n=1), Increase calmness and composure (n=2)
Wellbeing (n=6)	Mental well-being (n=4), Physical well-being* (n=2)
Cognitive rehabilitation* (n=4)	Cognitive rehabilitation* (n=4)
4. Existential Issues (n=8)	
Past, present and future (n=7)	Processing personal history (n=4), Reflecting self and future (n=3)
Meaning of life (n=1)	Spiritual, religious, or meaning issues (n=1)
5. Personal Growth (n=29)	
Attitude towards self (n=18)	Improve self-confidence, self-esteem (n=7)
	Improve self-acceptance (n=9), Understanding self* (n=2)
Desires and wishes (n=3)	Fulfilling desires and wishes (n=3)
Responsibility and self-control (n=4)	Assuming responsibility or learning to make decisions (n=3)
	Learning to delegate responsibility or decrease perfectionism (n=1)
Emotion regulation (n=4)	Learning to handle emotions (n=4)
6. Unknown (n=3)	
Unknown (n=3)	Unknown (n=3)

*Categories added to the Bern Inventory during process of exploration and categorisation of data

Figure 3 graphs the frequency of the goal categories within each goal type. The most common goal categories were Exercise and Activity (17.6%), Fears or Anxiety (16.3%) and Depressive Symptoms (13.7%). The least common included Relationship with Partner and Spiritual, Religious and Meaning Issues.

Figure 3: Frequency of Goal Units by Goal Category for Full Sample

P&S: Problems & Symptoms; I: Interpersonal; W&F: Wellbeing & Functioning; E: Existential; PG: Personal Growth; U: Unknown

3.3 Goal Orientation

Most (77.3%) goal units were categorised as approach-orientated (n=242). Table 2 shows the orientation of goals by goal type. The highest frequency of avoidance-orientated and 'unclear'

goals were Coping with Problems and Symptoms type goals. These goal units more frequently

used language such as 'get rid of', 'reduce' and have 'less' of unpleasant mental health

symptoms. They could also incorporate a combination of avoidant and approach-orientated

phrases in the same goal unit ('mobilise with more confidence/reduce anxiety') and language

that made the goal unit difficult to categorise ('work on' unpleasant symptoms). This may

account for findings. Approach-orientated goals were highest in frequency in Wellbeing and

Functioning type goals. Goals indicating a particular activity a person wished to engage in

were perhaps more clearly communicated as approach-orientated.

Table 2: Frequency of Goal Orientation by Goal Type

	Approach	Avoidance	Unclear
Coping with Specific Problems and Symptoms	108 (66.3%)	33 (20.2%)	22 (13.5%)
Interpersonal Problems	36 (85.7%)	3 (7.1%)	3 (7.1%)
Wellbeing and Functioning	64 (94.1%)	2 (2.9%)	2 (2.9%)
Existential Issues	7 (87.5%)	1 (12.5%)	0 (0%)
Personal Growth	24 (82.8%)	4 (13.8%)	1 (3.4%)
Unknown	3 (100%)		
Total	242 (77.3%)	43 (13.7%)	28 (9%)

3.4 Goal Attainment & Symptomatology

Only 59 clients (48.4% of sample) rated the attainment of their GBOs post-intervention. An

independent samples t-test found there was no significant difference in age for those who

provided attainment data (*M* = 71.95, *SD* = 7.22) and those that did not (*M* = 70.79, *SD* = 5.59; *t*(109.13), *p* =.33, two tailed). A Chi Squared Test for Independence (with Yates' Continuity Correction) indicated there was no significant difference in gender, χ^2 (1, *n* = 122) = .72, *p* = .40. The average goal attainment score was 7.2 (*SD* = 2.05), suggesting clients were mostly achieving their goals (scores ranged from 1.5-10).

Fifty three clients (43.4% of sample) completed a HADS post-intervention. Overall scores on the HADS A (*M* = 7.87, *SD* = 4.02) and HADS D (*M* = 5.92, *SD* = 4.13) were in the non-clinical range, suggesting on average clients benefitted from intervention.

Forty nine clients (40.2% of sample) completed both a GBO attainment rating and HADS post-intervention. This sample size is below the number required as per power calculation (n = 90). Preliminary bivariate correlations using Spearman's rho found a non-significant relationship between goal attainment and HADS A, *r* = -.276, CI [-.524,.014], *p* = .055, a significant but weak negative correlation between goal attainment and HADS-D, *r* = -.282, CI [-.528,-.007], *p* = .049, and a significant but low negative correlation between goal attainment and HADS Total, *r* = -.312, [-.551,-.025], *p* = .029. HADS A and HADS D were found to share 7.8% of their variance with goal attainment (R^2 = 7.8) and HADS Total to share 9.6% of variance (R^2 = 9.6). These preliminary findings suggest goal attainment ratings are capturing different changes to those reflected on a measure of symptomatology in an older adult population, as hypothesised, but should be treated with caution due to the insufficient sample size.

3.5 Goal Attainment by Goal Type

Average goal attainment ratings by goal type were calculated for the 59 clients with goal attainment data available. This provided 98 ratings of goal attainment by goal type. The goal type with the highest average attainment rating was 'Unknown'. Two clients set goals of this nature and fully achieved them (M = 10, SD = 0). These were very specific goals, suggesting clients were particularly motivated to achieve them. Coping with Problems and Symptoms had the second highest average attainment (M = 7.4, SD = 1.95), followed by Existential goals (M = 6.67, SD = 1.53) then Personal Growth (M = 6.46, SD = 2.73). Interpersonal goals (M = 6.27, SD = 2.67) and Wellbeing and Functioning (M = 6.27, SD = 2.2) had the lowest ratings. However, the means across the five goal types ranged from 6-7 out of 10. Figure 5 shows the median and spread of post-intervention attainment scores by goal type. Subjectively, there appears to be higher attainment ratings for Coping with Problems and Symptoms type goals, but due to the low frequency of attainment ratings for certain goal types, and variability in goal types rated within and between individuals, differences in attainment by goal type were not tested statistically. No conclusions can be therefore be drawn regarding goal type.

Figure 4: Box Plot of Average Goal Attainment by Goal Type
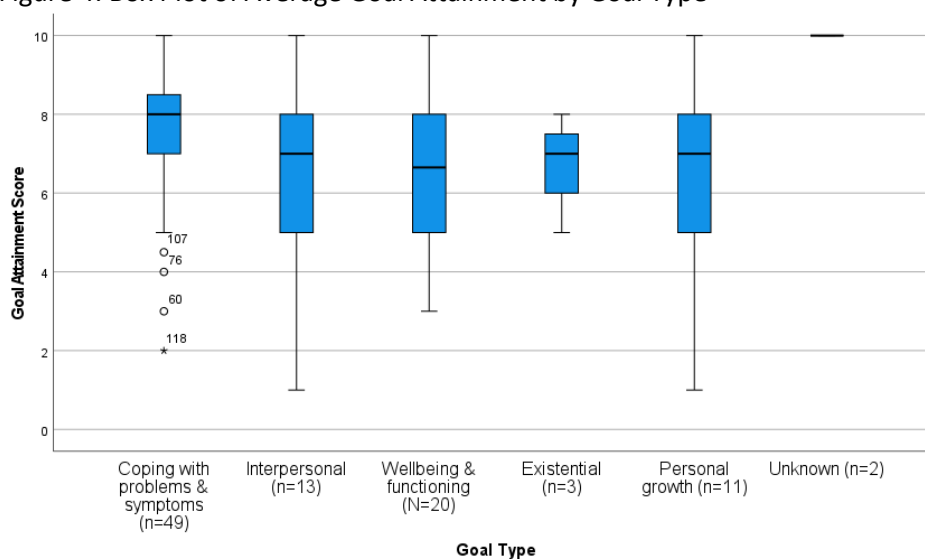
3.6 Goal Attainment by Goal Orientation

A Kruskal-Wallis Test revealed a statistically significant difference in goal attainment across the four goal orientations (exclusively approach, n=69; exclusively avoidance, n=1; unclear, n=2; or mixed, n=50), χ^2(2, n=59) = 8.04, *p* = .018. Clients who set exclusively approach-orientated goals recorded a significantly higher goal attainment rating (*Md* = 8) than clients who set mixed orientated goals (*p* =.005), *Md* = 6.75. This suggests clients setting exclusively approach-orientated goals are more likely to achieve them. However, these conclusions are limited due to the low frequency of avoidance-orientated goals in the analysis.

3.7 Goal Categorisation by Clinicians

Thirty two clinicians completed the goal categorisation task. The demographic characteristics of the sample are outlined in Table 3. Most of the participants were Clinical Psychologists (84.4%), female (84.4%) and experienced, with over a third qualified for 11+ years.

Table 3: Demographic Characteristics of Clinicians

Characteristics	n (%)
Profession	
Clinical Psychologist	27 (84.4%)
Other – Clinical Associate in Applied Psychology, CBT Therapist, Trainee Psychologist	5 (15.6%)
Gender	
Male	5 (15.6%)
Female	27 (84.4%)
Years qualified in profession	
0-2 Yrs	4 (12.5%)
3-5 Yrs	8 (25%)
6-10 yrs	8 (25%)
11+ yrs	12 (37.5%)
Experience in OAPSs	
0-2 Yrs	6 (18.8%)
3-5 Yrs	7 (21.9%)
6-10 Yrs	11 (34.4%)
11+ Yrs	8 (25%)

All participants categorised all 25 goal units in terms of goal type and goal orientation. Responses can be seen in Figure 5, a Heat map of percentage agreement on responses.

Figure 5: Heat Map of Clinicians' Categorisation of Goals by Type & Orientation

Goal Unit	Goal Type												Goal Orientation					
	Coping with problems & symptoms		Interpersonal		Wellbeing & functioning		Existential		Personal Growth		Unknown		Approach		Avoidance		Unclear	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
4. Better manage anxiety	32	100%											17	53.1%	9	28.1%	6	18.8%
11. Manage/reduce anxiety around rigid timings of events	32	100%											6	18.8%	22	68.8%	4	12.5%
15. Feel less anxious	32	100%											1	3.1%	31	96.9%		
25. Develop strategies to manage self-harm behaviours	32	100%											21	65.6%	7	21.9%	4	12.5%
1. Improve communication with others			31	96.9%							1	3.1%	32	100%				
7. Do more enjoyable activities/occupy time more					30	93.8%			2	6.3%			28	87.5%	1	3.1%	3	9.4%
22. Find healthier ways to manage low mood	30	93.8%			2	6.3%							24	75%	6	18.8%	2	6.3%
16. Go swimming					29	90.6%			3	9.4%			29	90.6%			3	9.4%
10. Improve self-esteem/confidence skills			2	6.3%	2	6.3%			28	87.5%			25	78.1%	2	6.3%	5	15.6%
5. Get back to where was previously in terms of activity	3	9.4%			27	84.4%			1	3.1%	1	3.1%	24	75%	4	12.5%	4	12.5%
9. Do my own shopping	2	6.3%			26	81.3%			2	6.3%	2	6.3%	29	90.6%			3	9.4%
19. Increase meaningful activity	2	6.3%			25	78.1%			4	12.5%	1	3.1%	31	96.9%			1	3.1%
2. Access support to maximise independence	1	3.1%			24	75%			7	21.9%			31	96.9%			1	3.1%

	C1	%	C2	%	C3	%	C4	%	C5	%	C6	%	C7	%	C8	%	C9	%
12. Gain clarity on reasons for memory decline	19	59.4%			3	9.4%	2	6.3%	3	9.4%	5	15.6%	23	71.9%	1	3.1%	8	25%
20. Be more assertive			19	59.4%					12	37.5%	1	3.1%	28	87.5%	2	6.3%	2	6.3%
21. Spend time with friends			18	56.3%	13	40.6%					1	3.1%	31	96.9%			1	3.1%
8. Accept diagnosis of osteoporosis	17	53.1%			3	9.4%	4	12.5%	7	21.9%	1	3.1%	24	75%	2	6.3%	6	18.8%
17. Have a healthier/better relationship with food	17	53.1%			12	37.5%			3	9.4%			26	81.3%	2	6.3%	4	12.5%
18. Find out about treatment options for difficulties	15	46.9%			2	6.3%			4	12.5%	11	34.4%	23	71.9%			9	28.1%
14. Freedom to live without darkness and despair	13	40.6%			1	3.1%	8	25%	2	6.3%	8	25%	2	6.3%	24	75%	6	18.8%
3. Be Happy	7	21.9%	1	3.1%	15	46.9%			2	6.3%	7	21.9%	19	59.4%	4	12.5%	9	28.1%
13. Understand own needs with regards to coping strategies, future supports	4	12.5%	1	3.1%	6	18.8%	1	3.1%	15	46.9%	5	15.6%	26	81.3%			6	18.8%
23. Delegate more/give away some control to others	1	3.1%	14	43.8%					14	43.8%	3	9.4%	24	75%			8	25%
6. Verbalise more easily past issues regarding work, parenting and relationships	2	6.5%	10	31.3%			12	37.5%	6	18.8%	2	6.3%	23	71.9%	3	9.4%	6	18.8%
24. Feel better	11	34.4%			8	25%	1	3.1%	2	6.3%	10	31.3%	9	28.1%	10	31.3%	13	40.6%

Scale - % agreement

0-19%	20-39%	40-59%	60-79%	80-100%

Goals related to mental health symptomatology resulted in higher levels of consensus about goal type, with anxiety and self-harm related goals achieving 100% agreement in the Coping with Problems and Symptoms category. Vaguer goals, such as 'to be happy' or 'feel better' led to greater variability, resulting in a spread of responses across goal types. Clear goals around increasing activity appeared to be more consistently rated as Wellbeing and Functioning. Placing goals into this category appeared more difficult when the activity involved socialising, splitting responses between Wellbeing and Functioning and Interpersonal goals. Goals more specific to older adults, such as understanding reasons for memory difficulties resulted in greater variability. These goals shaped the 'new additions' to the Bern Inventory and perhaps were not clear or well sited in the tool.

With regards to orientation, there was again better consensus around some goals than others. Goals that indicated the client wished to 'do', 'go', 'access' or 'improve' a desired state appeared to result in higher consensus around goals being approach-orientated (78.1-100%). Where goals stated the client wanted to feel 'less' of an undesired state, consensus around the goal being avoidance-orientated was at its highest (96.9%). As with goal type, vaguer goals around feeling better/happier appears to have resulted in lower consensus.

Inter-rater reliability for goal type was moderate, Light's Kappa = .48 and for goal orientation was fair, Light's Kappa= .32 (based on classification by Landis & Koch, 1977). Results suggest that, contrary to what was hypothesised, not all goals can be categorised into type reliably by clinicians. Results also suggest the orientation of goals is categorised less reliably than type.

4. Discussion

The aims of this study were to (1) investigate the types of goals older adults set in an OAPS (2) examine if mental health symptomatology correlates with goal attainment (3) explore if there are differences in goal attainment by goal type and (4) test if clinicians can reliably categorise goals.

4.1 Goal Types

Goals were found to belong to each of the five goal types contained within the Bern Inventory, a tool first developed with adult samples. Only a small number of goals were unable to be categorised, although additions were made at the goal category/sub-category level. New categories included Assessment and Diagnosis, to encompass neuropsychological assessment, and Cognitive Rehabilitation to cover goals around management of cognitive difficulties. At the sub-category level, Fear of Falling and Increasing Engagement in ADLS were also key additions. Any goal categorisation tools for use with older adults would need to consider these goals.

More than half the goals generated by clients in the OAPS belonged to the Coping with Problems and Symptoms goal type (52.1%), with goals around managing depression and anxiety featuring highly. This fits with literature on common mental health presentations amongst older adults (Ribeiro et al., 2020). Goals that belonged to the Wellbeing and Functioning goal type were also common (21.7%), particularly increasing exercise and activity levels. However, only 13.4% of goals were Interpersonal in nature. This is in contrast to research with adults, where Interpersonal goals were set by 74.5% of clients and Wellbeing and Functioning goals were only set by 13.4% (grosse Holtforth & Graw, 2002). This suggests older adults prioritise goals around returning to or increasing valuable activities, which fits with models of successful ageing (Baltes & Baltes, 1993). Perhaps increasing activities is viewed by older adults as a conduit to improving social connectedness. It is

interesting that Existential Issues featured infrequently, suggesting older adults do not have explicit goals around processing past experiences and reflecting on the self, as might be predicted based on Erikson's (1985) Life Stage model. Studies looking at goal types set by a range of client groups have found an absence of existential type goals (Bradley et al., 2013; Rupani et al., 2014).

Most goals were considered to be approach-orientated (77.3%), suggesting that setting GBOs may encourage an approach-orientated approach. However other factors, such as clinicians input, may be at play.

4.2 Goal Attainment and Symptomatology

There was a significant but weak correlation between clients' scores on a measure of symptomatology (HADS D & HADS Total) and their goal attainment rating, ranging from -.28 to -.31, sharing only 8.7% to 9.6% of variance. These findings are preliminary due to insufficient sample size. However, they are consistent with existing research (Smith et al., 2023; Wolpert et al., 2012) and provide tentative support for the use of GBOs in older adult settings. Using GBOs alongside, and to inform the choice of nomothetic measures (Jacob et al., 2017) could be useful clinically.

4.3 Goal Attainment by Goal Type/Orientation

The study data do not permit firm conclusions around whether goal attainment differs by goal type, and is therefore unable to add value to the inconsistent findings in this area (Berking et al., 2005, Rupani et al., 2014). Berking et al. (2005) found larger differences in goal attainment at the sub-category level of the Bern Inventory but again the data was too limited in this study to explore this. Findings do, however, suggest goal orientation may influence goal attainment, with clients who set

exclusively approach-orientated goals having significantly higher ratings of goal attainment. These findings are consistent with those found in student counselling services (Elliot & Church, 2002). This has clinical implications, suggesting clinicians should support clients to set consistent, approach-orientated goals.

4.4 Goal Type Agreement

Inter-rater reliability between multiple raters categorising goals into goal type was moderate in this study, and weaker than that found between two (Berking et al., 2005) and three raters (Rupani et al., 2014) in previous studies. However, it was clear when looking at the percentage levels of agreement that some goals were categorised into goal type more reliably than others and there were some patterns around the type and wording of goals that appeared to either facilitate or inhibit consensus around categorisation. Clinicians had limited orientation to, use, or training in the goal categorisation tool in this study. The context within which goals were set was not available to the clinician, unlike in natural settings. It may be that inter-rater reliability could be substantially improved if (1) clinicians were orientated and practised in a goal categorisation tool and (2) had contextual information regarding the client who was setting the goal. This is an area for further research and suggests there is still scope to explore the use of GBOs as part of evaluating psychological services.

The question of whether clinicians could reliably categorise goals into approach versus avoidance orientation was exploratory. Inter-rater reliability across multiple raters for goal orientation was fair. Similar to goal type, percentage agreement highlighted some goals had better consensus. Initial findings suggest clinicians have a sense of what approach and avoidance-orientated goals look like (responses were far from chance), but categorising goal orientations reliably requires more research.

4.5 Strengths of the research

This study explored the use of an outcome measurement that puts clients at the centre of plans for care and prioritises what is important to them, in a population previously not explored. The research has high ecological validity. It highlights areas that need addressed for GBOs to be used as a means for evaluating services.

4.6 Limitations of the research

No provisions (training, fidelity checks) were put in place to ensure clinicians within the service used the GBO tool in a standardised way. Therapy goals are generated in a relational context. How clinicians approach and record goals will be influential (Tryon, 2018). It therefore unclear how this lack of standardisation may have affected the findings and how the findings might generalise to other settings.

Another significant limitation was the extent of missing data. Data on service activity during the period of interest suggests GBOs were not recorded for a substantial proportion of clients. In addition, GBO attainment scores were only available for half of clients who generated GBOs. Perhaps post-intervention GBOs were only administered to 'treatment responders'. The initial plan had been to explore changes in goal attainment pre versus post-intervention, but a system issue led to poor recording of pre-intervention attainment scores. Measuring change based solely on a post-intervention ratings overlooks the extent of change.

A singular nomothetic measure was used to capture changes in symptomatology. This measure is designed to screen for symptoms of depression and anxiety. It is unknown what the presenting problems of clients were but it is reasonable to assume the HADS was not sensitive to detect changes across the full range of clients' symptoms. The addition of other measures could have improved the study.

Lastly, clients generated up to three goals for therapy; no primary goal was identified. Goal attainment was an aggregate attainment score of each goal. However, goals could be heterogeneous. Findings based on overall goal attainment scores should be treated with caution.

4.7 Further research

More robust studies with larger samples exploring whether goal type influences goal attainment are needed, and whether findings around goal attainment and orientation can be replicated. Analysing changes in goal attainment scores from pre to post-intervention, rather than solely post-attainment scores would be recommended. Testing out whether clinician training in the use of GBO and goal categorisation tools might increase both the utilisation of a GBO measure and the reliability of goal categorisation by clinicians would also be recommended. Qualitative research around the process of generating and measuring change using GBOs from the clients perspective is needed (McLeod & Mackrill, 2018).

5. Conclusions

Older adults generate unique goals when engaging with psychological services. Some types of goals may be more reliably attained than others. Idiographic measures might enable services to capture changes in clients' progress beyond symptomatology. This research sheds light on what might be needed to collate changes on goal attainment at a service level.

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Appendix 1:1: PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	Page 6
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist. (*Journal limit of 200 words so unable to fulfil full criteria)	Page 7
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Page 8-12
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Section 1.4
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Section 2.2
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Section 2.1
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Page 90
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Section 2.3
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Section 2.4
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Section 2.5
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Section 2.4
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	Section 2.6

Section and Topic	Item #	Checklist item	Location where item is reported
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	Section 2.5
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5).	Section 2.7
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	N/A
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Section 2.7
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Section 2.7
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	Section 2.7
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	N/A
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	Section 2.6
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	Section 2.6
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Page 17
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Page 16
Study characteristics	17	Cite each included study and present its characteristics.	Page 19
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Page 32
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Page 23-30
Results of	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Page 33-36

Section and Topic	Item #	Checklist item	Location where item is reported
syntheses	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	N/A
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	N/A
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	N/A
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	Page 32
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	Page 33-36
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Section 4.1
	23b	Discuss any limitations of the evidence included in the review.	Section 4.1
	23c	Discuss any limitations of the review processes used.	Section 4.2
	23d	Discuss implications of the results for practice, policy, and future research.	Section 4.2
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Page 13
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Page 13
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	N/A
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review. (*will include in publication)	
Competing interests	26	Declare any competing interests of review authors. (*will include in publication)	
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review. (*will include in publication)	

Appendix 1.2: Protocol for Systematic Review

URL: https://osf.io/y4jcs

Appendix 1.3: Search Strategy

PsychInfo

1. DE "Treatment" OR DE "Addiction Treatment" OR DE "Adjunctive Treatment" OR DE "Adventure Therapy" OR DE "Aftercare" OR DE "Alternative Medicine" OR DE "Anxiety Management" OR DE "Behavior Modification" OR DE "Bibliotherapy" OR DE "Brief Interventions" OR DE "Caregiving" OR DE "Patient Transfer" OR DE "Patient Treatment Matching" OR DE "Cognitive Behavior Therapy" OR DE "Cognitive Stimulation Therapy" OR DE "Cognitive Techniques" OR DE "Computer Assisted Therapy" OR DE "Counseling" OR DE "Creative Arts Therapy" OR DE "Cross Cultural Treatment" OR DE "Culturally Adapted Interventions" OR DE "Disease Management" OR DE "Habilitation" OR DE "Health Care Services" OR DE "Horticulture Therapy" OR DE "Hospice" OR DE "Human Potential Movement" OR DE "Human Services" OR DE "Hydrotherapy" OR DE "Institutionalization" OR DE "Integrated Services" OR DE "Interdisciplinary Treatment Approach" OR DE "Intervention" OR DE "Involuntary Treatment" OR DE "Language Therapy" OR DE "Life Sustaining Treatment" OR DE "Maintenance Therapy" OR DE "Medical Treatment (General)" OR DE "Mental Health Programs" OR DE "Milieu Therapy" OR DE "Mind Body Therapy" OR DE "Mindfulness-Based Interventions" OR DE "Movement Therapy" OR DE "Multimodal Treatment Approach" OR DE "Multisystemic Therapy" OR DE "Outpatient Treatment" OR DE "Pain Management" OR DE "Partial Hospitalization" OR DE "Personal Therapy" OR DE "Physical Treatment Methods" OR DE "Private Practice" OR DE "Psychoeducation" OR DE "Psychotherapy" OR DE "Rehabilitation" OR DE "Relaxation Therapy" OR DE "Respite Care" OR DE "Self-Help Techniques" OR DE "Sex Therapy" OR DE "Social Casework" OR DE "Sociotherapy" OR DE "Speech Therapy" OR DE "Spiritual Care" OR DE "Strengths-Based Interventions" OR DE "Symptoms Based Treatment" OR DE "Therapeutic Processes" OR DE "Transdiagnostic Treatment" OR DE "Trauma-Informed Care" OR DE "Trauma Treatment" OR DE "Treatment Guidelines" OR DE "Treatment Outcomes" OR DE "Treatment Planning" OR DE "Video-Based Interventions"

2. SU "psychol* intervention" OR TI "psychol* intervention" OR AB "psychol* intervention

3. SU "psychol* treatment" OR TI "psychol* treatment" OR AB "psychol* treatment"

4. SU psychotherap* OR TI psychotherap* OR AB psychotherap*

5. SU therap* OR TI therap* OR AB therap*

6. S1 OR S2 OR S3 OR S4 OR S5

7. DE "Feedback" OR DE "Biofeedback" OR DE "Delayed Feedback" OR DE "Knowledge of Results" OR DE "Sensory Feedback"

8. SU feedback OR TI feedback OR AB feedback

9. S7 OR S8

10. DE "Treatment Process and Outcome Measures" OR DE "Patient Reported Outcome Measures"

11. SU monitor* OR TI monitor* OR AB monitor*

12. SU outcome* OR TI outcome* OR AB outcome*

13. SU progress* OR TI progress* OR AB progress*

14. SU OQ-45 OR TI OQ-45 OR AB OQ-45

15. SU PCOMS OR TI PCOMS OR AB PCOMS

16. S10 OR S11 OR S12 OR S13 OR S14 OR S15

17. DE "Treatment Outcomes" OR DE "Psychotherapeutic Outcomes" OR DE "Side Effects (Treatment)" OR DE "Treatment Compliance" OR DE "Treatment Duration" OR DE "Treatment Refusal" OR DE "Treatment Termination" OR DE "Treatment Withholding"

18. SU effect* OR TI effect* OR AB effect*

19. SU effic* OR TI effic* OR AB effic*

20. S17 OR 18 OR S19

21. S6 AND S9 AND S16 AND S20

22. DE "Mental Health Services" OR DE "Community Mental Health Services" OR DE "Psychological First Aid"

23. SU "mental health*" OR TI "mental health*" OR AB "mental health*"

24. SU psychiat* OR TI psychiat* OR AB psychiat*

25. S22 OR S23 OR S24

26. S21 AND S25

27. Narrow by language - English

CINAHL

1. (MH "Psychotherapy+")

2. TI "psychol* intervention" OR AB "psychol* intervention" OR SU "psychol* intervention"

3. TI "psychol* treatment" OR AB "psychol* treatment" OR SU "psychol* treatment"

4. TI psychotherap* OR AB psychotherap* OR SU psychotherap*

5. TI therap* OR AB therap* OR SU therap*"

6. S1 OR S2 OR S3 OR S4 OR S5

7. (MH "Feedback")

8. TI feedback OR AB feedback OR SU feedback

9. S7 OR S8

10. (MH "Outcomes (Health Care)") OR (MH "Outcome Assessment") OR (MH "Patient-Reported Outcomes+") OR (MH "Treatment Outcomes")

11. TI monitor* OR AB monitor* OR SU monitor*

12. TI outcome* OR AB outcome* OR SU outcome*

13. TI progress* OR AB progress* OR SU progress*

14. TI OQ-45 OR AB OQ-45 OR SU OQ-45

15. TI PCOMS OR AB PCOMS OR SU PCOMS

16. S10 OR S11 OR S12 OR S13 OR S14 OR S15

17. TI effect* OR AB effect* OR SU effect*

18. TI effic* OR AB effic* OR SU effic*

19. S17 OR S18

20. S6 AND S9 AND S16 AND S19

21. (MH "Mental Health Services+")

22. TI "Mental health*" OR AB "Mental health*" OR SU "Mental health*"

23. TI psychiat* OR AB psychiat* OR SU psychiat*

24. S21 OR S22 OR S23

25. S20 AND S24

26. Narrow by language - English

Medline

Search Strategy:

1. exp Psychotherapy/

2. psychotherap*.mp.

3. "psychol* intervention".mp.

4. "psychol* treatment".mp.

5. therap*.mp.

6. S1 OR S2 OR S3 OR S4 OR S5

7. feedback.mp.

8. exp Feedback, Psychological/

9. S7 OR S8

10. exp "Outcome and Process Assessment, Health Care"/

11. monitor*.mp.

12. outcome*.mp.

13. progress*.mp.

14. OQ-45.mp.

15. PCOMS.mp.

16. S10 OR S11 OR S12 OR S13 OR S14 OR S15

17. exp treatment outcome/

18. effect*.mp.

19. effic*.mp.

20. S17 OR S18 OR 19

21. S6 AND S9 AND S16 AND S20

22. exp Mental Health Services/

23. "mental health*".mp.

24. psychiat*.mp.

25. S22 OR S23 OR S24

26. S21 AND S25

27. Limit 26 to English language

Embase

1. exp Psychotherapy/

2. psychotherap*.mp.

3. "psychol* intervention".mp.

4. "psychol* treatment".mp.

5. therap*.mp.

6. S1 OR S2 OR S3 OR S4 OR S5

7. exp psychological feedback/

8. feedback.mp.

9. S7 OR S8

10. monitor*.mp

11. outcome*.mp.

12. progress*.mp.

13. OQ-45.mp.

14. PCOMS.mp.

15. S10 OR S11 OR S12 OR S13 OR S14

16. exp treatment outcome/ or exp clinical outcome/ or exp minimal clinically important difference/ or exp outcome assessment/ or exp outcomes research/ or exp patient-reported outcome/ or exp treatment failure

17. effect*.mp.

18. effic*.mp.

19. S16 OR S17 OR S18

20. S6 AND S9 AND S15 AND S19

21. exp Mental Health Care/

22. "mental health*".mp.

23. psychiat*.mp.

24. S21 OR S22 OR S23

25. S20 AND S24

26. Limit 25 to English language

Cochrane Review

1. MeSH descriptor: [Psychotherapy] explode all trees

2. (psychol* NEXT intervention):ti,ab,kw

3. (psychol* NEXT treatment):ti,ab,kw

4. (psychotherap*):ti,ab,kw

5. (therap*):ti,ab,kw

6. #1 OR #2 OR #3 OR #4 OR #5

7. MeSH descriptor: [Feedback, Psychological] explode all trees

8. (feedback):ti,ab,kw

9. #7 OR #8

10. MeSH descriptor: [Outcome Assessment, Health Care] explode all trees

11. (monitor*):ti,ab,kw

#12. (outcome*):ti,ab,kw

13. (progress*):ti,ab,kw

14. (OQ-45):ti,ab,kw

15. (PCOMS):ti,ab,kw

16. #10 OR #11 OR #12 OR #13 OR #14 OR #15

17. MeSH descriptor: [Treatment Outcome] explode all trees

18. (effect*):ti,ab,kw

19. (effic*):ti,ab,kw

20. #17 OR #18 OR #19

21. #6 AND #9 AND #16 AND #20

22. MeSH descriptor: [Mental Health Services] explode all trees

23. (mental NEXT health*):ti,ab,kw

24. (psychiat*):ti,ab,kw

25. #22 OR #23 OR #24

26. #21 AND #25

27. Excluded - Cochrane Reviews

The International Standard Randomised Controlled Trial Number Registration

1. Condition: Mental Health

2. Intervention: Feedback

Filter: Study status "completed"

The US National Institutes of Health clinical trials database

1. Condition: Mental Health

2. Intervention: Feedback

Filter: Study status "completed"

Appendix 2.1: Major Research Project Proposal

URL: https://osf.io/4kwyx/

Appendix 2.2: NHS Research Ethics Committee Approval Letter

East of Scotland Research Ethics Service (EoSRES)

NHS
SCOTLAND
Research Ethics Service

TAyside medical Science Centre
Residency Block Level 3
George Pirie Way
Ninewells Hospital and Medical School
Dundee DD1 9SY

Professor Hamish McLeod	Date:	21 June 2023
Professor of Clinical Psychology & Doctorate in	Your Ref:	
Clinical Psychology Programme Director	Our Ref:	LR/23/ES/0019
School of Health & Wellbeing	Enquiries to:	Mrs Lorraine Reilly
University of Glasgow	Direct Line:	
1st Floor, Admin Building	Email:	tay.eosres@nhs.scot
Gartnavel Royal Hospital, 1055 Great Western		
Road, Glasgow G12 OXH		

Dear Professor McLeod

Study title:	Using a Goal Based Outcomes approach in an Older Adult Psychology Service: Goal types generated, their attainmentâ€¯and if they can be categorised reliably
REC reference:	23/ES/0019
IRAS project ID:	325409

Thank you for your letter of 19 June 2023, responding to the Research Ethics Committee's (REC) request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants

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Conditions of the favourable opinion

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

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

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 management permissions from host organisations

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered on** a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as:

- clinical trial of an investigational medicinal product
- clinical investigation or other study of a medical device
- combined trial of an investigational medicinal product and an investigational medical device
- other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by the HRA (for more information on registration and requesting a deferral see: Research registration and research project identifiers).

If you have not already included registration details in your IRAS application form you should notify the REC of the registration details as soon as possible.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

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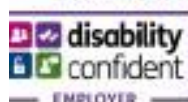
Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

It is the 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).

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, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to

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Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [IRAS325409 UoG Insurance Client Information Letter 17Feb23]		20 July 2022
Interview schedules or topic guides for participants [IRAS325409 Staff Participant Task Instructions V2 05May2023]	2	05 May 2023
Interview schedules or topic guides for participants [IRAS325409 Qualtrics Goal Categorisation Task Sample Question V2 05May23]	2	05 May 2023
IRAS Application Form [IRAS_Form_19062023]		19 June 2023
IRAS Checklist XML [Checklist_19062023]		19 June 2023
Letters of invitation to participant [IRAS325409 Recruitment Email V2 05May2023]	2	05 May 2023
Non-validated questionnaire [IRAS325409 Demographic Information V2 17feb23]	2	17 February 2023
Other [IRAS325409 Caldicott Guardian Access Request Form V1 03Feb23]		
Other [IRAS325409 DPIA V2.2 27March2023]		31 January 2023
Other [IRAS325409 List of Measures V3 05May23]	3	05 May 2023
Other [IRAS325409 Protocol V3 06June2023 CLEAN]	3	06 June 2023
Other [IRAS325409Provisional Opinion amendments V2 06June2023.]	2	06 June 2023
Participant consent form [IRAS325409 Consent Form Version 4.1 12June2023 TRACKEDCHANGES]	4.1	12 June 2023
Participant consent form [IRAS325409 Consent Form Version 4.1 12June2023 CLEAN VERSION]	4.1	12 June 2023
Participant consent form [IRAS325409 Privacy Notice V1.2 02June2023 TRACKEDCHANGES]	1.2	02 June 2023
Participant consent form [IRAS325409 Privacy Notice V1.2 02June2023 CLEANVERSION]	1.2	02 June 2023
Participant information sheet (PIS) [IRAS325409 Participant Information Sheet Version 3.1 12June2023 TRACKED CHANGES]	3.1	12 June 2023
Participant information sheet (PIS) [IRAS325409 Participant Information Sheet Version 3.1 12June2023 CLEANVERSION]	3.1	12 June 2023
Research protocol or project proposal [IRAS325409 Protocol V3 06June2023 TRACKED CHANGES]	3	06 June 2023
Summary CV for Chief Investigator (CI) [IRAS325409 CV Chief Investigator Professor Hamish McLeod V1 25Jan23]		24 January 2023
Summary CV for student [IRAS325409 CV Principal Investigator V1 20Jan23]		20 January 2023

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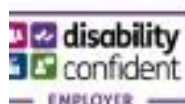
Summary CV for supervisor (student research) [IRAS325409 CV Field Supervisor H Hockaday V1 25Jan23]		24 January 2023
Validated questionnaire [IRAS325409 Measure 1 GoalBasedOutcomes V1]		
Validated questionnaire [IRAS325409 Measure 2 HADS SeePg8-10.]		
Validated questionnaire [IRAS325409 Measure 3 BernInventory]		04 April 2012

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.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at:
https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 325409   Please quote this number on all correspondence

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

Yours sincerely

pp
Dr Robert Rea
Chair

Email: tay.eosres@nhs.scot

Enclosures: After ethical review – guidance for researchers

Copy to: Emma-Jane Gault

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Appendix 2.3: NHS Research Ethics Application Amendment 1

Amendment Tool

v1.6 06 December 2021

For office use

QC: No

Section 1: Project information

Short project title*:	A Goal Based Outcomes approach in Older Adult Psychology Services, V1
IRAS project ID* (or REC reference if no IRAS project ID is available):	IRAS 325409
Sponsor amendment reference number*:	IRAS 325409 AM01
Sponsor amendment date* (enter as DD/MM/YY):	24 July 2023
Briefly summarise in lay language the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study. If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained (note: this field will adapt to the amount of text entered)*:	The NHS Generic Reviewer (NHS GG&C) requested that the IRAS reference number for the study be added to all research documentation where this wasn't included. They also requested a 'easy read' version of the research proposal. They also asked that insurance details were added to the Patient Information Leaflet. These documents are being submitted as a minor ammendment. These changes have no significance for the proposed study.

	Specific study
Project type (select):	Research tissue bank
	Research database

Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	**Yes**	No

	NHS/HSC REC
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	Ministry of Defence (MoDREC)

Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a **modified amendment** (i.e. a substantial amendment previously given an unfavourable opinion)?	Yes	**No**

	England	Wales	Scotland	Northern Ireland
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	No	No	**Yes**	No

Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	Yes	**No**
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	Yes	**No**
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	Yes	**No**
Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:	Yes	**No**
Did the study involve adults lacking capacity OR does the amendment introduce this?:	Yes	**No**
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	Yes	**No**
Did the study involve prisoners or young offenders who are in custody or supervised by the probation service OR does the amendment introduce this?:	Yes	**No**
Did the study involve children OR does the amendment introduce this?:	Yes	**No**
Did the study involve NHS/HSC organisations prior to this amendment?:	**Yes**	No
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	Yes	**No**

	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	No	No	**Yes**	No
Which nations had participating NHS/HSC organisations prior to this amendment?	No	No	**Yes**	No
Which nations will have participating NHS/HSC organisations after this amendment?	No	No	**Yes**	No

Does this study only involve a single participating NHS organisation in Scotland?	Yes	**No**

Section 2: Summary of change(s)

Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the Amendment Tool as three separate changes. A list of all possible changes is available on the "Glossary of Amendment Options" tab. To add another change, click the "Add another change" box.

Change 1					
Area of change (select)*:	Study Documents				
Specific change (select - only available when area of change is selected first)*:	Other minor change to study documents (e.g. information sheets, consent forms, questionnaires, letters) that can be implemented within existing resource in place at participating organisations - Please specify in the free text below				
Further information In particular, please describe why this change can be implemented within the existing resource in place at the participating organisations (free text - note that this field will adapt to the amount of text entered)*	Insertion of IRAS Reference Number to the following documents: Staff Participant Task Instructions v2.1 21/07/2023; Participant Information Sheet v3.2 07/07/2023; Demographic information v2.1 21/07/2023; DPIA v2.3 21/07/2023; List of Measures v3.1 21/07/2023; Measure 1 Goal based outcomes v1.1 21/07/2023; Privacy Notice v1.3 21/07/2023; Qualtrics Goal Categorisation Task Sample Question v2.1 21/07/2023. Insurance details included in the Patient Information Sheet V3.2 07/07/2023. A Plain Language Summary v1 07/07/2023 has been developed.				
Applicability:		England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:		No	No	Yes	No
Will all participating NHS/HSC organisations be affected by this change, or only some? (please note that this answer may affect the categorisation for the change):		All		Some	

Remove all changes below

Change 2					
Area of change (select)*:	Study Documents				
Specific change (select - only available when area of change is selected first)*:	Protocol - Non-substantial changes (e.g. not affecting safety or the scientific value of the trial)				
Further information (free text - note that this field will adapt to the amount of text entered):	Insertion of IRAS reference number to Protocol v3.1 21/07/2023				
Applicability:		England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:		No	No	Yes	No
Will all participating NHS/HSC organisations be affected by this change, or only some? (please note that this answer may affect the categorisation for the change):		All		Some	

Add another change

Section 3: Declaration(s) and lock for submission

Declaration by the Sponsor or authorised delegate

- I confirm that the Sponsor takes responsibility for the completed amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

Name [first name and surname]*:	Emma-Jane Gault
Email address*:	emmajane.gault@glasgow.ac.uk

Lock for submission

Please note: This button will only become available when all mandatory (*) fields have been completed. When the button is available, clicking it will generate a locked PDF copy of the completed amendment tool which must be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

Lock for submission

After locking the tool, proceed to submit the amendment online. The "Submission Guidance" tab provides further information about the next steps for the amendment.

Section 4: Review bodies for the amendment

Please note: This section is for information only. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

Review bodies

	UK wide:						England and Wales:				Scotland:				Northern Ireland:				Category:
	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	UKSW Governance	REC (MCA)	CAG	HMPPS	HRA and HCRW Approval	REC (AWMA)	PBPP	SPS (RAEC)	National coordinating function	HSC REC	HSC Data Guardians	Prisons	National coordinating function	
Change 1:						(Y)								(Y)					C
Change 2:						(Y)								(Y)					A
Overall reviews for the amendment:																			
Full review:						N								N					
Notification only:						Y								Y					
Overall amendment type:	Non-substantial, no study-wide review required																		
Overall Category:	A																		

Appendix 2.4: NHS Research Ethics Application Amendment 2

Amendment Tool
v1.6 06 December 2021

Section 1: Project information

Short project title*:	A Goal Based Outcomes approach in Older Adult Psychology Services, V1
IRAS project ID* (or REC reference if no IRAS project ID is available):	IRAS 325409
Sponsor amendment reference number*:	IRAS 325409 AM02
Sponsor amendment date* (enter as DD/MM/YY):	18 August 2023
Briefly summarise in lay language the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study. If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained (note: this field will adapt to the amount of text entered)*:	As part of the previous amendment, the PIS was updated to v3.2 7July23. In error, this revised version number and date were not updated in the corresponding consent form. This is corrected now with an updated Consent Form v4.2 8August23.

	Specific study	
Project type (select):		
	Research tissue bank	
	Research database	

Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	Yes	No
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	NHS/HSC REC	
	Ministry of Defence (MoDREC)	
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a **modified amendment** (i.e. a substantial amendment previously given an unfavourable opinion)?	Yes	No

Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	No	No	Yes	No

Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	Yes	No
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	Yes	No
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	Yes	No
Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:	Yes	No
Did the study involve adults lacking capacity OR does the amendment introduce this?:	Yes	No
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	Yes	No
Did the study involve prisoners or young offenders who are in custody or supervised by the probation service OR does the amendment introduce this?:	Yes	No
Did the study involve children OR does the amendment introduce this?:	Yes	No
Did the study involve NHS/HSC organisations prior to this amendment?:	Yes	No
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	Yes	No

	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	No	No	Yes	No
Which nations had participating NHS/HSC organisations prior to this amendment?	No	No	Yes	No
Which nations will have participating NHS/HSC organisations after this amendment?	No	No	Yes	No

Does this study only involve a single participating NHS organisation in Scotland?	Yes	No

Section 2: Summary of change(s)

Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the Amendment Tool as three separate changes. A list of all possible changes is available on the "Glossary of Amendment Options" tab. To add another change, click the "Add another change" box.

Change 1					
Area of change (select)*:	Study Documents				
Specific change (select - only available when area of change is selected first)*:	Other minor change to study documents (e.g. information sheets, consent forms, questionnaires, letters) that can be implemented within existing resource in place at participating organisations - Please specify in the free text below				
Further information In particular, please describe why this change can be implemented within the existing resource in place at the participating organisations (free text - note that this field will adapt to the amount of text entered)*	Consent Form updated to reference current version of Participant Information Sheet (Version 3.2, 7July23), replacing the superseded version. No other changes have been made.				
Applicability:		England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:		No	No	**Yes**	No
Will all participating NHS/HSC organisations be affected by this change, or only some? (please note that this answer may affect the categorisation for the change):		All		Some	
					Add another change

Section 3: Declaration(s) and lock for submission

Declaration by the Sponsor or authorised delegate

• I confirm that the Sponsor takes responsibility for the completed amendment tool
• I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

Name [first name and surname]*:	Emma-Jane Gault
Email address*:	emmajane.gault@glasgow.ac.uk

Lock for submission

Please note: This button will only become available when all mandatory (*) fields have been completed. When the button is available, clicking it will generate a locked PDF copy of the completed amendment tool which must be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

> **Lock for submission**

After locking the tool, proceed to submit the amendment online. The "Submission Guidance" tab provides further information about the next steps for the amendment.

Section 4: Review bodies for the amendment

Please note: This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

	Review bodies																
	UK wide:					England and Wales:				Scotland:				Northern Ireland:			
	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	UKSW Governance	REC (MCA)	CAG	HMPPS	HRA and HCRW Approval	REC (AWMA)	PBPP	SPS (RAEC)	National coordinating function	HSC REC	HSC Data Guardians	Prisons	National coordinating function	Category:
Change 1:						(Y)								(Y)					C
Overall reviews for the amendment:																		
Full review:						N								N				
Notification only:						Y								Y				
Overall amendment type:	Non-substantial, no study-wide review required																
Overall Category:	C																

Appendix 2.5: NHS Ayrshire & Arran Approval Letter

NHS Ayrshire & Arran

Research & Development
56a Lister Street
University Hospital Crosshouse
Kilmarnock
KA2 0BB

Prof Hamish McLeod	Date	2nd August 2023
University of Glasgow	Your Ref	
School of Health & Wellbeing	Our Ref	CM/KLB/AK 2023AA019
1st Floor, Admin Building		
Gartnavel Royal Hospital,	Enquiries to	Karen Bell
Glasgow	Extension	25850
G12 0XH	Direct line	
	Fax	
	Email	Karen.Bell2@aapct.scot.nhs.uk

Dear Prof McLeod

Using a Goal Based Outcomes approach in an Older Adult Psychology Service: Goal types generated, their attainment and if they can be categorised reliably

I confirm that NHS Ayrshire and Arran have reviewed the undernoted documents and grant R&D Management approval for the above study.

Documents received:

Document	Version	Date
Localised OID	1.0	08/05/2023
IRAS Form	6.3.5	25/04/2023
Protocol	3.1	21/07/2023
Recruitment email	2.0	05/05/2023
PIS	3.2	07/07/2023
Consent Form	4.1	12/06/2023
Demographic Information	2.1	21/07/2023
DPIA	2.3	21/07/2023
Privacy notice	1.3	21/07/2023
Staff Participant Task Instructions	2.1	21/07/2023
Qualtrics Goal Categorisation Task	2.1	21/07/2023
List of Measures	3.1	21/07/2023
Plain Language Summary	1.0	07/07/2023
Measure 1: Goal Based Outcome	1.1	21/07/2023
Measure 2: HADS	-	-
Measure 3: BernInventory	-	-
Schedule of Events	1.0	31/01/2023

The terms of approval state that the investigator authorised to undertake this study within NHS Ayrshire & Arran is: -

- Mrs Katie Phillips, Trainee Clinical Psychologist, NHS Ayrshire & Arran

With additional investigators:-

- Dr Harriet Hockaday, Clinical Psychologist, NHS Ayrshire & Arran

The sponsors for this study are University of Glasgow.

This approval letter is valid until 1st October 2024.

Regular reports of the study require to be submitted. Your first report should be submitted to Dr K Bell, Research & Development Manager in 12 months time and subsequently at yearly intervals until the work is completed.

Please note that as a requirement of this type of study your name, designation, work address, work telephone number, work e-mail address, work related qualifications and whole time equivalent will be held on the Scottish National Research Database so that NHS R&D staff in Scotland can access this information for purposes related to project management and report monitoring.

In addition approval is granted subject to the following conditions: -

- All research activity must comply with the standards detailed in the UK Policy Framework for Health and Social Care Research http://beta.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research and appropriate statutory legislation. It is your responsibility to ensure that you are familiar with these, however please do not hesitate to seek further advice if you are unsure.

- Recruitment figures must be submitted to R&D on a monthly basis. If recruitment figures are not received timeously you will be contacted by a member of the R&D team to provide this data.

- You are required to comply with Good Clinical Practice (ICH-GCP guidelines may be found at www.ich.org/LOB/media/MEDIA482.pdf), Ethics Guidelines, Health & Safety Act 1999, General Data Protection Regulation (GDPR) and Data Protection Act 2018.

- If any amendments are to be made to the study protocol and or the Research Team the Researcher must seek Ethical and Management Approval for the changes before they can be implemented.

- The Researcher and NHS Ayrshire and Arran must permit and assist with any monitoring, auditing or inspection of the project by the relevant authorities.

- The NHS Ayrshire and Arran Complaints Department should be informed if any complaints arise regarding the project and the R&D Department must be copied into this correspondence.

- The outcome and lessons learnt from complaints must be communicated to funders, sponsors and other partners associated with the project.

- As custodian of the information collated during this research project you are responsible at all times for ensuring the security of all personal information collated in line with NHS Scotland policies on information assurance and security, until the secure destruction of these data. The retention time periods for such data should comply with the requirements of the Scottish Government Records Management: NHS Code Of Practice. Under no circumstances should personal data be stored on any unencrypted removable media e.g. laptop, USB or mobile device (for further information and guidance please contact the Information Governance Team based at University Hospital Crosshouse   ).

If I can be of any further assistance please do not hesitate to contact me. On behalf of the department, I wish you every success with the project.

Yours sincerely

Dr Crawford McGuffie
Medical Director

c.c.   Emma-Jane Gault, University of Glasgow (sponsor contact)
       Lesley Douglas, Finance, Ailsa Hospital
       Information Governance, NHS Ayrshire & Arran
       Katie Phillips, NHS Ayrshire & Arran
       Dr Harriet Hockaday, NHS Ayrshire & Arran
       Dr Morag Henderson, Clinical Director

Appendix 2.6: Major Research Project Protocol

URL: https://osf.io/4kwyx

Appendix 2.7: APA Journal Article Reporting Standards

APA Style JARS
Journal Article Reporting Standards

JARS–Quant | Table 1
Information Recommended for Inclusion in Manuscripts
That Report New Data Collections Regardless of Research Design

Title and Title Page

Title

- Identify main variables and theoretical issues under investigation and the relationships between them.
- Identify the populations studied.

Author Note

- Provide acknowledgment and explanation of any special circumstances, including
  - registration information if the study has been registered
  - use of data also appearing in previous publications
  - prior reporting of the fundamental data in dissertations or conference papers
  - sources of funding or other support
  - relationships or affiliations that may be perceived as conflicts of interest
  - previous (or current) affiliation of authors if different from location where the study was conducted
  - contact information for the corresponding author
  - additional information of importance to the reader that may not be appropriately included in other sections of the paper

Abstract

Objectives

- State the problem under investigation, including main hypotheses.

Participants

- Describe subjects (nonhuman animal research) or participants (human research), specifying their pertinent characteristics for the study; in animal research, include genus and species. Participants are described in greater detail in the body of the paper.

Study Method

- Describe the study method, including
  - research design (e.g., experiment, observational study)
  - sample size
  - materials used (e.g., instruments, apparatus)
  - outcome measures
  - data-gathering procedures, including a brief description of the source of any secondary data. If the study is a secondary data analysis, so indicate.

Findings

- Report findings, including effect sizes and confidence intervals or statistical significance levels.

Conclusions

- State conclusions, beyond just results, and report the implications or applications.

Introduction

Problem

- State the importance of the problem, including theoretical or practical implications.

Review of Relevant Scholarship

- Provide a succinct review of relevant scholarship, including
  - relation to previous work
  - differences between the current report and earlier reports if some aspects of this study have been reported on previously

Hypothesis, Aims, and Objectives

- State specific hypotheses, aims, and objectives, including
  - theories or other means used to derive hypotheses
  - primary and secondary hypotheses
  - other planned analyses
- State how hypotheses and research design relate to one another.

Method

Inclusion and Exclusion

- Report inclusion and exclusion criteria, including any restrictions based on demographic characteristics.

Participant Characteristics

- Report major demographic characteristics (e.g., age, sex, ethnicity, socioeconomic status) and important topic-specific characteristics (e.g., achievement level in studies of educational interventions).
- In the case of animal research, report the genus, species, and strain number or other specific identification, such as the name and location of the supplier and the stock designation. Give the number of animals and the animals' sex, age, weight, physiological condition, genetic modification status, genotype, health–immune status, drug or test naïveté, and previous procedures to which the animal may have been subjected.

JARS–**Quant** | Table 1 | Page 1 of 3

Sampling Procedures

- Describe procedures for selecting participants, including
  - sampling method if a systematic sampling plan was implemented
  - percentage of sample approached that actually participated
  - whether self-selection into the study occurred (either by individuals or by units, such as schools or clinics)
- Describe settings and locations where data were collected as well as dates of data collection.
- Describe agreements and payments made to participants.
- Describe institutional review board agreements, ethical standards met, and safety monitoring.

Sample Size, Power, and Precision

- Describe the sample size, power, and precision, including
  - intended sample size
  - achieved sample size, if different from the intended sample size
  - determination of sample size, including
    › power analysis, or methods used to determine precision of parameter estimates
    › explanation of any interim analyses and stopping rules employed

Measures and Covariates

- Define all primary and secondary measures and covariates, including measures collected but not included in the report.

Data Collection

- Describe methods used to collect data.

Quality of Measurements

- Describe methods used to enhance the quality of measurements, including
  - training and reliability of data collectors
  - use of multiple observations

Instrumentation

- Provide information on validated or ad hoc instruments created for individual studies, for individual studies (e.g., psychometric and biometric properties).

Masking

- Report whether participants, those administering the experimental manipulations, and those assessing the outcomes were aware of condition assignments.
- If masking took place, provide a statement regarding how it was accomplished and whether and how the success of masking was evaluated.

Psychometrics

- Estimate and report values of reliability coefficients for the scores analyzed (i.e., the researcher's sample), if possible. Provide estimates of convergent and discriminant validity where relevant.
- Report estimates related to the reliability of measures, including
  - interrater reliability for subjectively scored measures and ratings
  - test–retest coefficients in longitudinal studies in which the retest interval corresponds to the measurement schedule used in the study
  - internal consistency coefficients for composite scales in which these indices are appropriate for understanding the nature of the instruments being used in the study
- Report the basic demographic characteristics of other samples if reporting reliability or validity coefficients from those samples, such as those described in test manuals or in norming information for the instrument.

Conditions and Design

- State whether conditions were manipulated or naturally observed. Report the type of design as per the JARS–Quant tables:
  - experimental manipulation with participants randomized
    › Table 2 and Module A
  - experimental manipulation without randomization
    › Table 2 and Module B
  - clinical trial with randomization
    › Table 2 and Modules A and C
  - clinical trial without randomization
    › Table 2 and Modules B and C
  - nonexperimental design (i.e., no experimental manipulation): observational design, epidemiological design, natural history, and so forth (single-group designs or multiple-group comparisons)
    › Table 3
  - longitudinal design
    › Table 4
  - N-of-1 studies
    › Table 5
  - replications
    › Table 6
- Report the common name given to designs not currently covered in JARS–Quant.

Data Diagnostics

- Describe planned data diagnostics, including
  - criteria for post-data-collection exclusion of participants, if any
  - criteria for deciding when to infer missing data and methods used for imputation of missing data
  - definition and processing of statistical outliers
  - analyses of data distributions
  - data transformations to be used, if any

Analytic Strategy

- Describe the analytic strategy for inferential statistics and protection against experiment-wise error for
  - primary hypotheses
  - secondary hypotheses
  - exploratory hypotheses

Results

Participant Flow

- Report the flow of participants, including
  - total number of participants in each group at each stage of the study
  - flow of participants through each stage of the study (include figure depicting flow, when possible; see the JARS–Quant Participant Flowchart)

Recruitment

- Provide dates defining the periods of recruitment and repeated measures or follow-up.

Statistics and Data Analysis

- Provide information detailing the statistical and data-analytic methods used, including
  - missing data
    - frequency or percentages of missing data
    - empirical evidence and/or theoretical arguments for the causes of data that are missing—for example, missing completely at random (MCAR), missing at random (MAR), or missing not at random (MNAR)
    - methods actually used for addressing missing data, if any
  - descriptions of each primary and secondary outcome, including the total sample and each subgroup, that includes the number of cases, cell means, standard deviations, and other measures that characterize the data used
  - inferential statistics, including
    - results of all inferential tests conducted, including exact p values if null hypothesis significance testing (NHST) methods were used, and reporting the minimally sufficient set of statistics (e.g., dfs, mean square [MS] effect, MS error) needed to construct the tests
    - effect-size estimates and confidence intervals on estimates that correspond to each inferential test conducted, when possible
    - clear differentiation between primary hypotheses and their tests–estimates, secondary hypotheses and their tests–estimates, and exploratory hypotheses and their test–estimates

Statistics and Data Analysis (continued)

- complex data analyses—for example, structural equation modeling analyses (see also Table 7), hierarchical linear models, factor analysis, multivariate analyses, and so forth, including
  - details of the models estimated
  - associated variance–covariance (or correlation) matrix or matrices
  - identification of the statistical software used to run the analyses (e.g., SAS PROC GLM or the particular R package)
- estimation problems (e.g., failure to converge, bad solution spaces), regression diagnostics, or analytic anomalies that were detected and solutions to those problems.
- other data analyses performed, including adjusted analyses, if performed, indicating those that were planned and those that were not planned (though not necessarily in the level of detail of primary analyses).
- Report any problems with statistical assumptions and/or data distributions that could affect the validity of findings.

Discussion

Support of Original Hypotheses

- Provide a statement of support or nonsupport for all hypotheses, whether primary or secondary, including
  - distinction by primary and secondary hypotheses
  - discussion of the implications of exploratory analyses in terms of both substantive findings and error rates that may be uncontrolled

Similarity of Results

- Discuss similarities and differences between reported results and work of others.

Interpretation

- Provide an interpretation of the results, taking into account
  - sources of potential bias and threats to internal and statistical validity
  - imprecision of measurement protocols
  - overall number of tests or overlap among tests
  - adequacy of sample sizes and sampling validity

Generalizability

- Discuss generalizability (external validity) of the findings, taking into account
  - target population (sampling validity)
  - other contextual issues (setting, measurement, time; ecological validity)

Implications

- Discuss implications for future research, program, or policy.

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JARS–**Quant** | Table 3
Reporting Standards for Studies Using No Experimental Manipulation
(Single-Group Designs, Natural-Group Comparisons, etc.; In Addition to Material Presented in Table 1)

Title/Abstract

Study Design

- Describe the design of the study.

Data Use

- State the type of data used.

Method

Participant Selection

- Describe the method(s) of selecting participants (i.e., the units to be observed, classified, etc.), including
  - method(s) of selecting participants for each group (e.g., methods of sampling, place of recruitment) and the number of cases in each group
  - matching criteria (e.g., propensity score), if matching was used
- Identify the data sources used (e.g., sources of observations, archival records), and if relevant, include codes or algorithms used to select participants or link records.

Variables

- Define all variables clearly, including
  - exposure
  - potential predictors, confounders, and effect modifiers
- State how each variable was measured.

Comparability of Assessment

- Describe the comparability of assessment across groups (e.g., the likelihood of observing or recording an outcome in each group for reasons unrelated to the effect of the intervention).

Analysis

- Describe how predictors, confounders, and effect modifiers were included in the analysis.

Discussion

Limitations

- Describe potential limitations of the study. As relevant, describe the possibility of misclassification, unmeasured confounding, and changing eligibility criteria over time.

Appendix 2.8: Goal Taxonomy Tool – Approach/Avoidance-orientated goals

URL: https://osf.io/4kwyx/

Appendix 2.9: Adapted Bern Inventory

Bern Inventory of Therapy Goals (BIT-T, v.4)

Taxonomy of Treatment Goals, adapted for Older Adult population

Goal Category 1: Coping with specific problems & symptoms	
Goals around improving/reducing specific problems or symptoms. Examples are listed below, divided into sub-categories. This list is not exhaustive. There may be goals that fit this category that aren't specified below.	
Sub-category	Examples
Depressive Symptoms	Negative thoughts Negative moods Loss of drive/energy Other specific goals in this category Goal not otherwise specified
Suicidality & Self Injury	Self-Injurious behaviour Suicidality Other specific goals in this category Goal not otherwise specified
Fears or Anxiety	Fears/Anxiety in specific situations (including *fear of falling) Panic attacks Social phobic fears *General anxiety *Physical symptoms of anxiety Other specific goals in this category Goal not otherwise specified
Obsessive thoughts and compulsive behaviours	Obsessions and compulsions
Coping with trauma	Traumas
Substance use and addiction	Somatic withdrawal Changing addictive behaviours Other specific goals in this category Goal not otherwise specified
Eating behaviours	Coping with problematic eating behaviours (anorexia, bulimia) Obesity Other specific goals in this category Goals not otherwise specified
Sleep	Sleeping problems
Sexuality	Sexual problems
Coping with somatic problems	Pain Chronic illnesses *Anxiety around persistent physical symptoms Other specific goals in this category (OSG) Goals not otherwise specified (NOS)

Difficulties in specific life domains/ Stress	Stress Housing problems Work and education Time management Other specific goals in this category Goals not otherwise specified
*Anger	*Anger
*Assessment/Diagnosis	*Assessment – Neuropsychological *Assessment – Mental health
Medication	Medication
Other specific goals in this category	
Not otherwise specified	

Goal Category 2: Interpersonal Problems

Goals around relationships with others. Examples are listed below, divided into sub-categories. This list is not exhaustive. There may be goals that fit this category that aren't specified below.

Sub-category	Examples
Current relationship	Relationship with partner, spouse, or significant other Improve sex-life with partner, spouse, or significant other Expectations, feelings related to partner, spouse or significant other Other specific goals in this category Goals not otherwise specified
Current family	Parenthood Family situation Other specific goals in this category Goals not otherwise specified
Family of origin	Family of origin
Other specific relationships	Other specific relationships
Loneliness and grief	Coping with loneliness Grieving loss
Assertiveness and boundary issues	Assertive behaviours Cognitive/emotional readiness for assertiveness Other specific goals in this category Goals not otherwise specified
Connectedness and intimacy	Increase frequency and quality of interpersonal contact Permitting intimacy Prepare for new relationship Other specific goals in this category Goals not otherwise specified
Other specific goals in this category	
Goals not otherwise specified	

Goal Category 3: Wellbeing and Functioning

Goals around improving mental and physical wellbeing. Examples are listed below, divided into sub-categories. This list is not exhaustive. There may be goals that fit this category that aren't specified below.

Sub-category	Examples
Exercise and Activity	Increase exercise *Improve mobility Improve leisure activities *Increase engagement in ADLs Other specific goals Goals not otherwise specified
Relaxation and Composure	Learn to relax Increase calmness and composure Other specific goals in this category Goals not otherwise specified
Well-being	Mental well-being (including self-care) *Physical well-being Sense of comfort with body Other specific goals in this category Goals not otherwise specified
*Cognitive rehabilitation	*Cognitive rehabilitation
Other specific goals in this category	
Goals not otherwise specified	

Goal Category 4: Existential Issues

Goals around making sense of life and looking for meaning. Examples are listed below, divided into sub-categories. This list is not exhaustive. There may be goals that fit this category that aren't specified below.

Sub-category	Examples
Past, present and future	Processing personal history Reflecting self and future Other specific goals in this category Goals not otherwise specified
Meaning of Life	Spiritual, religious, or meaning issues
Other specific goals in this category	
Goals not otherwise specified	

Goal Category 5: Personal Growth	
Goals around developing personally in areas such as confidence, assertiveness and management of emotions. Examples are listed below, divided into sub-categories. This list is not exhaustive. There may be goals that fit this category that aren't specified below.	
Sub-category	Examples
Attitude towards self	Improve self-confidence, self-esteem Improve self-acceptance *Understand self Other specific goals in this category Goals not otherwise specified
Desires and Wishes	Recognising desires and wishes Fulfilling desires and wishes Other specific goals in this category Goals not otherwise specified
Responsibility and Self-Control	Assuming responsibility or learning to make decisions Learning to delegate responsibility or decrease perfectionism Other specific goals in this category Goals not otherwise specified
Emotion Regulation	Learning to handle emotions
Other specific goals in this category	
Goals not otherwise specified	

Goal Category: Unknown
Goals that cannot be categorised into one of the categories above

*Categories added to Bern Inventory during exploration and categorisation of Data

Reference: Grosse Holtforthe, M., & Grawe, K. (2002). BERN INVENTORY OF TREATMENT GOALS: PART 1. Development and First Application of a Taxonomy of Treatment Goal Themes. Psychotherapy research, 12(1), 79-99. doi:10.1080/713869618

Appendix 2.10: Participant Information Sheet

URL: https://osf.io/4kwyx/

Appendix 2.11: Consent Form

URL: https://osf.io/4kwyx/

Appendix 2.12: Privacy notice

URL: https://osf.io/4kwyx/

Appendix 2.13: Participants Task Instructions

URL: https://osf.io/4kwyx