Real-world evidence in a UK veteran's charity

Summary:

This report provides preliminary findings from PTSD Resolution's Project-100 study, investigating the efficacy of Human Givens therapy for treating psychological trauma in military veterans. Using established outcome measures (CORE-10, PHQ-9, GAD-7, PCL-5), initial results suggest promising recovery and consistent improvement rates, aligning with or surpassing national standards.

The therapy, marked by superior client engagement and lower dropout rates, demonstrates its acceptance among veterans. Acknowledging challenges in conducting randomised controlled trials, the report highlights the value of complementary real-world research as per the NICE Guidelines. It underlines the importance of client feedback and personalised treatment plans.

Preliminary evidence suggests the Human Givens therapy approach, implemented by PTSD Resolution, shows promise for addressing veteran psychological trauma. Further long-term follow-up data is needed for a comprehensive understanding of the therapy's efficacy.

Key findings

- The overwhelming majority of clients who contact the service progress into treatment, with more than 3 out of 4 clients staying in treatment to an agreed planned ending.
- Treatment effect sizes are large on all measures used.
- Recovery rates are broadly equivalent to the ambitious targets set by the Improving Access to Psychological Therapies Services with very high numbers of referrals engaging in treatment.
    - 73% of clients self-refer (27% are referred from other organisations)
    - 94% of initial enquiries progress to screening
    - 94% of those screened progress to therapy
    - 95% of those who start therapy have at least 2 sessions
    - 77.44% of clients who start therapy remain in treatment to an agreed planned ending
    - 24.22% of referrals are female
    - 21.37% of referrals are family members of veterans
    - >90% data completion for sessional measures
    - Average number of treatment sessions was 6.4
    - Recovery rates on combined GAD-7 & PHQ-9 measures were 49.62% (reliable recovery 46.56%)
    - Reliable recovery rates on PCL-5 are 61.63% for clients who stay to an agreed planned ending
    - Reliable improvement rates: PCL-5 68.14%, GAD-7 67.81%, PHQ-9 54.93%
    - Effect sizes on all measures are large (>1)

PTSD Resolution- Initial report on 12 months data -April 2022 to March 2023

PTSD Resolution (https://ptsdresolution.org/) is a UK-based charity that provides treatment for military veterans, reservists, and their families who are struggling with post-traumatic stress disorder (PTSD) and other mental health conditions related to their service. The charity was established in 2009 and operates across the UK, with a network of over 200 accredited Human Givens therapists who offer treatment services to those in need. The charity plays a vital role in providing prompt and tailored treatment services to military personnel and their families who are struggling with a wide range of mental health conditions.

In May 2019 Burdett and Greenberg published the King's Centre for Military Health research evaluation of PTSD Resolution (Burdett & Greenberg, 2019). They concluded that the services PTSD Resolution offers appear to be an acceptable alternative to treatment offered through the Improving Access to Psychological Therapies programme (IAPT-(Wakefield et al., 2021) but they highlighted the challenge of direct comparison because of the use of different measures to IAPT. They further suggested that evidence derived from randomised controlled trials (RCT) would add more weight to the evidence base.

While it is indeed an aspiration of PTSD Resolution to participate in such an RCT this poses a considerable challenge for reasons that are well understood. In fact, the National Institute for Health and Care Excellence (NICE -https://www.nice.org.uk/) recognises the challenge for organisations such as PTSD Resolution and suggest an alternative or complementary approach to the accumulation of evidence; Real-World Evidence (RWE).

RWE refers to evidence that is collected from routine clinical practice and includes data from a wide range of patients with varying characteristics, comorbidities, and treatment histories. RWE provides a high level of external validity, as it reflects the outcomes of

interventions in real-world settings which can provide insights into the effectiveness of interventions in real-world practice.

In recognition of the need for the use of RWE to be more commonplace, especially where routinely collected data are involved, in June 2022 the NICE published a RWE framework that provides a road map to its production (https://www.nice.org.uk/about/what-we-do/real-world-evidence-framework) . While it is made clear that RCTs are the preferred source of evidence for determining the effects of interventions, NICE points out that RCTs are sometimes unavailable or are not directly relevant to decisions about patient care. The conduction of RCTs may be unethical or unfeasible, randomisation may simply be too difficult or impractical or funding may not be available. All of the above are relevant for PTSD Resolution.

Clients self-refer or are referred by other organisations to PTSD Resolution. No diagnosis is required. Following initial telephone contact the clients are invited to a telephone screening appointment with an administrator. Following completion of this process where the client can explain about their current problems and where they can learn about the treatment on offer, should the client wish to be treated they are referred on to a therapist. PTSD Resolution refers clients exclusively to fully qualified and accredited Human Givens therapists. Human Givens therapy (HG) (https://www.hgi.org.uk/human-givens) is a relatively new form of therapy that draws on a range of psychological theories and techniques to help individuals overcome emotional distress and mental health issues. It focuses on the innate emotional needs that humans have, including the need for security, connection, achievement, attention, autonomy, and meaning, and aims to help individuals meet these needs in healthy ways. The significance of using only HG therapy to treat the veterans who access the services of PTSD Resolution is that it provides a non-invasive, non-pharmaceutical approach that is tailored to each individual's specific needs. It is a

collaborative therapy that provides a holistic and effective approach to mental health treatment that is grounded in an understanding of the fundamental emotional needs of individuals, empowering them to take an active role in their recovery and helps them to develop new coping skills and strategies.

Previous investigation of HG

The effectiveness of HG has been investigated through an original study of a similar design to Project-100 [Luton Study- (Andrews et al., 2011)] and later through a much larger practice-based study conducted through the HG practice research network [PRN- (Andrews et al., 2013)]. More details about the network, including a description of the HG treatment for trauma that is commonly used with PTSD Resolution clients can be found in the book chapter on the development of a Practice Research Network in the International Handbook of Workplace Trauma Support, (pp 213–226, Andrews & Miller, 2012). Currently, the HG PRN has data on over 5000 closed cases. PTSD Resolution, similarly, has data on over 2,500 closed cases.

Aligned with the principles of the NICE RWE framework, PTSD Resolution published their protocol for the conduction of their RWE study, named Project-100, which commenced in April 2023.
The protocol :-
https://ptsdresolution.org/pdf/protocolfinal.pdf
provides a comprehensive outline of the intentions behind the study. The work is ongoing but as the first anniversary has just passed it was considered important to provide an overview of some of the initial results so that these could be made available while the work goes on towards publication in a peer reviewed journal.

Ethical approval

The chair of ethics at the University of Roehampton was provided with the protocol and consulted with regard to the need for formal ethical approval. Because the study was a service evaluation audit, using routinely collected data it was confirmed that it was not necessary to have a formal ethical review.

The client journey

As explained above, the client journey with PTSD Resolution begins when the veteran or family member contacts the charity as a self-referral (255, 73%) or the person has been referred to the charity by another organisation (96, 27%). The admin team member who takes the call explains about the charity, has a discussion and offers a telephone screening appointment. The person attends their telephone screening appointment, a comprehensive appointment that takes on average 30 minutes. At the end of this if the person wishes to proceed to an appointment with a therapist,, the client is assigned to a qualified HG therapist who then contacts them directly to set up their appointment. Typically, within a couple of weeks, the client will attend their first appointment with a therapist. The majority of clients attend for 6 appointments, but the possibility is there to extend treatment if this is considered necessary and likely to be beneficial. Since April 1st, 2022, the majority of clients are tracked within Project-100. A number of clients (n=72) of the total who were referred in the time period (N=351) are not included in the study for ethical and practical reasons that will be explained in the section below on demographics. The remaining clients were all included in the Project-100 study for this time period (n=279).

We wanted to profile the clients as accurately as possible over a given period. The client numbers on the journey through the charity is illustrated by referring to table 1 below.

Table 1 Project-100 The client journey

Referral pathway		
	n	%
Total initial enquiries	375	
Declined screening	24	6.40%
Attended screening	351	93.60%
Not for P-100	72	20.50%
Project-100 commencers	279	79.50%
Project-100 currently in therapy	105	37.63%
Project-100 therapy ended	174	62.37%
Only attended screening	10	5.74%
Attended at least 1 session with therapist	164	94.25%
Attended only 1 session with therapist	9	5.17%
Attended at least 2 sessions with a therapist	155	89.08%
No. of unplanned endings of those who engaged in treatment (attended at least 2 sessions)	28	18.06%
No. of planned endings of those who engaged in treatment (attended at least 2 sessions)	127	81.94%

As outlined in table 1 above, 24 clients who made an initial enquiry failed to complete the referral process by not calling the charity back to arrange a screening appointment. PTSD Resolution considers a client to be a 'referral' once the screening process has been completed and the client has been assigned to a therapist. In the 12 month period from April 1st 2023 351 clients completed the referral process.

Of those clients included in the Project-100 study who referred in the first 12-month period (April 1, 2022 to March 31, 2023) there were 174 closed clients, with 105 clients currently remaining in treatment.

Attrition

Considering the 174 closed cases, referring to table 1 above one can see that just 10 clients (5.74%) failed to attend their first therapy session with a therapist following screening. An additional 9 clients (5.17%) attended just 1 session with a therapist. 155 clients (89.08% of completed referrals) attended 2 or more sessions. 127 (81.94%) of these 155 clients stayed on in treatment to an agreed planned ending.

Demographics

To provide a comprehensive profile of all referrals demographic data of all 351 clients in the referral period are provided.

Table 2 - All referrals (Gender / employment / living arrangements / age)

Client Numbers	
P-100 Clients	279
Non P100 Clients	72
Total	351

Gender	
Female	85
Male	263
Not Given	3
Total	351

Employment	
No information	25
Working	182
Student	14
Signed off from working	60
Seeking Work	20
Retired	35
Not working/seeking work	15
Total	351

Living arrangements	
No information	4
Alone	111
With Family	191
Homeless	8
Prison	13
Supported Accommodation	7
Home Share	17
Total	351

Age	
<25	17
25 - 29	16
30 - 34	29
35 - 39	48
40 - 44	59
45 - 49	47
50 - 54	45
55 - 59	28
60 - 64	27

>65	35
Total	351

Table 3 All referrals (Ethnicity / medication / veteran or family member)

Ethnicity	
No information	19
African	1
Any Other	1
Black British	2
Carribean	2
Not stated	8
Other Mixed	2
Other White	5
White and Black Carribean	1
White British	309
White Irish	1
Total	351

Medication	
No information	81
Anti-Depressants	114
Anti-Psychotics	4
None	119
Other	33
Total	351

Veteran or Family member	
No information	11
Veteran	265
Family Member	75
Total	351

Table 4 All referrals (Disability / service / years of service /rank)

Disability	
No information	177
None	108
Other physical	46
PTSD	20
Total	351

Service	
NA/Private	4
Army	278
Marines	7
Navy	25
RAF	37
Total	351

Years of service	
<5	69
5 - 9	108
10 - 20	90
>20	73
Not stated	11
Total	351

Rank	
No information	20
Private	144
JNCO	81
SNCO	87
Officer	19
Total	351

Table 5 Clients not included in the study

Non P-100 Clients	
Child	6
Client not suitable	11
Client request	11
Extension of pre P100	1
HMP	14
No email	10
No information	1
No internet access	3
No pc	2
Private	1
Therapist unable	12
Total	72

Table 5 illustrates the number of clients who were not included and the reasons. PTSD Resolution recognises the extra burden on clients of participation in an audit process that requires completion of many measures at repeated time-points and when for any practical or ethical reason it was considered inappropriate then the client was excluded from the study. For example, clients in prison were not in a position to be able to complete measures. Some therapists, while excellent therapists, for various reasons find managing anything to do with forms and measures impracticable. Some clients felt unable to cooperate with the demands of participation and sometimes it was at the discretion of the administration team to consider a client unsuitable. Minors were not included, as were clients without internet access or email (wherever possible, the therapists provided links to the measures by email through the outcomes management software, Pragmatic Tracker, in order to diminish therapist effects on the client completing measures and in order to do this the client needed to be able to receive emails).

Measures choice for use in Project-100

GAD-7

The General Anxiety Disorder -7 (GAD-7) is a self-report questionnaire designed to assess the severity of generalized anxiety disorder (GAD) in adults. It consists of seven items that ask about the frequency of anxiety symptoms over the past two weeks, rated on a 4-point scale from 0 (not at all) to 3 (nearly every day). The scores for each item are summed to give a total score that ranges from 0 to 21, with higher scores indicating more severe anxiety symptoms. In IAPT a person is said to be at caseness, or suffering with clinical anxiety, when their GAD-7 symptom score is 8 or above. The GAD-7 is widely used in clinical practice and research to screen for and monitor the severity of anxiety symptoms, as well as to evaluate the effectiveness of interventions.

PHQ-9

The Patient Health Questionnaire-9 (PHQ-9) is a self-report measure used to assess the presence and severity of depression in adults. It consists of nine questions, each of which assesses one of the diagnostic criteria for major depressive disorder in the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5™, 5th Ed., 2013). The clinical interpretation of PHQ-9 scores is as follows:

0-4: Minimal or no depression

5-9: Mild depression

10-14: Moderate depression

15-19: Moderately severe depression

20 and above: Severe depression. In IAPT a person is said to be at caseness, or suffering with clinical depression, when their PHQ-9 symptom score is 10 or above.

The PHQ-9 is widely used in clinical practice and research to screen for and monitor the severity of depression in patients, and has been found to have good reliability and validity as a measure of depression.

GAD-7 and PHQ-9 are consistently used together in IAPT services as the basis for measuring the outcomes of the IAPT services and therapeutic interventions. For this reason PTSD Resolution made the decision to include them on a session by session basis as a part of the protocol.

PCL-5

The Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5) is a self-report measure used to assess the symptoms of posttraumatic stress disorder (PTSD) in individuals who have experienced a traumatic event. It is brief and easy to administer. It consists of 20 items and can be completed in approximately 5-10 minutes. This makes it a practical tool for use in clinical settings or research studies. The PCL-5 includes items that assess all four symptom clusters of PTSD as defined in the DSM-5: intrusion symptoms, avoidance symptoms, negative alterations in cognitions and mood, and alterations in arousal and reactivity.

The total score on the PCL-5 ranges from 0 to 80, with higher scores indicating more severe PTSD symptoms. Some authorities suggest that the severity of PTSD symptoms can be classified based on the following cut-off scores:

No PTSD: Total score less than 33 (in IAPT a score of 32 is used)

Mild PTSD: Total score between 33 and 36

Moderate PTSD: Total score between 37 and 48

Severe PTSD: Total score of 49 or higher

It's worth noting that these cut-offs are not meant to be used as diagnostic criteria, but rather as indicators of symptom severity. While a diagnosis of PTSD should be made by a qualified mental health professional based on a comprehensive assessment, self-report scores on the PCL-5 as used by the HG therapists in this study, act as an indicator of 'probable PTSD' with the higher scores above 32 being more indicative.
The PCL-5 has been shown to have good internal consistency, test-retest reliability, and convergent and divergent validity with other measures of trauma-related symptoms.
The PCL-5 has been used in a variety of settings, including clinical, research, and military populations. Its widespread use allows for comparison of results across different populations. It can be administered before and after treatment to assess changes in PTSD symptoms over time. This can be useful for tracking treatment progress and evaluating the effectiveness of different interventions.

The PCL-5 is the IAPT measure of choice for use in assessing the presence and severity of PTSD as well as monitoring change in treatment. Because many PTSD Resolution clients suffer with the aftermath of traumatic events the PCL-5 was included for routine use before and after treatment and at follow up.

CORE-10

The Clinical Outcome in Routine Evaluation, 10 item brief measure (CORE-10) is a brief self-report questionnaire used to assess general psychological distress in individuals. It consists of 10 questions that inquire about the individual's emotional state, behavior, and overall well-being. The questions are rated on a 5-point Likert scale, ranging from 0 (not at all) to 4 (most or all the time), with higher scores indicating greater levels of distress. The questions cover areas such as anxiety, depression, physical symptoms, and relationships.

The CORE-10 is designed to be a reliable and valid measure of distress and is commonly used in clinical settings, such as in therapy or counseling. It is also used in research studies as an outcome measure to assess changes in psychological distress over time.
The cutoff scores for the CORE-10 are as follows:
0-9: Minimal distress
10-17: Mild distress
18-29: Moderate distress
30-39: Severe distress
40-40: Extreme distress
It is important to note that the cutoff scores may vary depending on the population being assessed and the purpose of the evaluation. As a general rule of thumb, a clinical cut-off score of 11 is frequently used, with scores of 11 or higher indicating distress. It is recommended to interpret the scores in the context of the individual's overall clinical picture and to use clinical judgment when making treatment decisions.

The CORE-10 has also been included as a session-by-session measure in Project-100 because the measure has been used by PTSD Resolution for well over a decade. This study provides an opportunity to test whether change can be measured satisfactorily by CORE-10 in a similar way to GAD-7 and PHQ-9. If this indeed proves to be the case, it widens choice for therapists, it reduces burden on clients if CORE-10 were to be used as a replacement for GAD-7 and PHQ-9 and it provides some retrospective validation of the decade of results PTSD Resolution already has.

Reliable change index

The reliable change index (RCI) is a statistical method used to determine whether a change in a patient's score on an outcome measure is meaningful and beyond what would be

expected due to measurement error or natural variation in scores. The RCI is calculated by comparing a patient's pre- and post-treatment scores on an outcome measure and taking into account the reliability of the measure.

If the difference between the two scores equals or exceeds the RCI, it suggests that the change in the patient's score is statistically reliable, or, in other words, the change is likely to be a true change and not simply a result of natural variation or measurement error.

The RCI is important because it helps clinicians and researchers determine whether a treatment or intervention has had a meaningful impact on a patient's symptoms or functioning. By comparing the pre- and post-treatment scores on an outcome measure with the RCI, clinicians and researchers can determine whether the change in scores is clinically significant and whether the treatment or intervention has been effective.

The RCI scores for the 4 above measures are as follows:

GAD-7 > or = 4

PHQ-9 > or = 6

PCL-5 > or = 10

CORE-10 > or = 6

Table 6 Data quality (no. & % of clients who were measured at pre- and post-treatment)

Data quality				
	Pre-treatment		Post-treatment	
Attended at least 1 session with therapist	164			
GAD-7	155	94.50%	146	94.19%
PHQ-9	153	93.30%	142	92.81%
CORE-10	159	96.95%	146	91.82%
PCL-5	150	91.50%	113	75.33% *(89%)**

Data quality (see table 6 above) is important because in order to have increased confidence in results one needs to know that the highest number of clients possible are included in the evaluation.

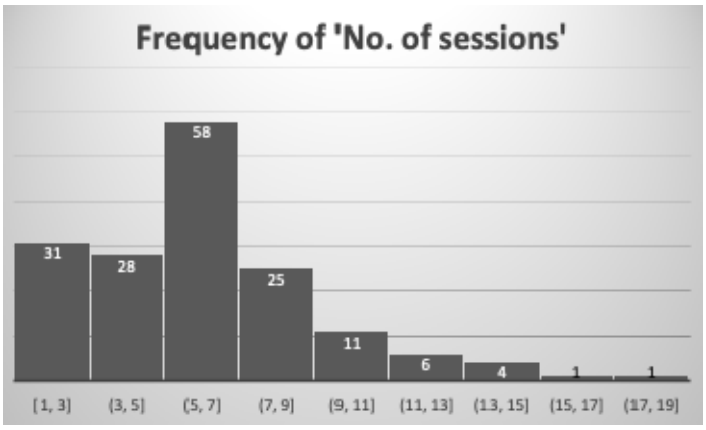
For those measures used session by session (CORE-10, GAD-7, PHQ-9) data quality was greater than 90%. In the case of PCL-5, as this was used at pre- and post-treatment only, the post-treatment percentage drops to 75% which reflects the 3 out of 4 clients who stayed in treatment to an agreed planned ending.

** The 89% represents the fact that the 113 of 127 clients who stayed to an agreed planned ending were measured at a 2nd time-point with PCL-5.*

No. of treatment sessions

The mean number of treatment sessions (including the assessment appointment) was 6.4 with a range from 1 to 18. The frequency chart in figure 1 below demonstrates that the majority of clients had between 5 and 9 sessions.

Figure 1: No. of treatment sessions attended



Paired samples statistics and calculation of effect size

The purpose of a paired samples T-test with repeated measures data is to compare the means of two related or paired groups, where each participant is measured twice or more under different conditions. In other words, this test is used to determine whether there is a significant difference between the means of two related groups on the same dependent variable, typically before and after an intervention, treatment, or exposure.

By using a paired samples T-test on the 4 measures under discussion (GAD-7, PHQ-9, PCL-5 and CORE-10), we were able to determine whether the observed changes from the 1st pre-treatment score and the last available score (post treatment when clients stay to an agreed planned ending, or the last available when clients prematurely terminate) are statistically significant and not simply due to chance or measurement error. Because comparison of the pre- and post-treatment means in all cases demonstrate significant differences, we then went on to investigate the effect size with the different measures.

Effect Size is the difference between the means of measure scores before and after treatment, expressed in standard deviations. A more positive value indicates a more beneficial effect. As a general rule an effect size of 0.8 or higher is considered to be a large effect.

The case report results for these 4 measures used in Project-100 over the 12 months from April 1, 2022, with clients who either completed treatment with an agreed planned ending, or otherwise prematurely terminated treatment are published in the tables below, with explanation following each table. Effect sizes are provided on each table. Full explanation of effect size calculation is provided at https://pragmatictracker.com/help3/effectsize.php.

Table 7 Results from Project-100 closed cases measured with GAD-7 & PHQ-9

	Primary		Secondary			
Measure	GAD-7	%	PHQ-9-c	%	Both	%
First Appt	155		153		153	
Later Appts	146	94.19	142	92.81	142	92.81
Cases	130	89.04	115	80.99	131	92.25
Recovered	72	55.38	59	51.3	65	49.62
Reliably Recovered	71	54.62	54	46.96	61	46.56
Reliably Improved	99	67.81	78	54.93		
Effect Size						
Cohen's d	1.1728		1.0144			
Hedges' g*	1.1698		1.0117			

The universal approach to reporting on IAPT data is to use the GAD-7 (anxiety) and PHQ-9 (depression) measures as the means of establishing improvement rates in treatment. IAPT

defines ‘treatment completers’ as clients who have more than 1 measurement time point available with the measure(s) of interest, regardless of whether a client completed treatment or dropped out prematurely.

Looking at GAD-7, there were 155 clients with a 1st GAD-7 measure completed and 146 clients who completed at least 1 additional GAD-7 (attended at least 2 appointments). Of the 146 who had a 1st and at least 1 other GAD-7 130 of these were scoring at ‘caseness’, that is, at or above the clinical cut-off of the measure, which for GAD-7 is a score of 8. Therefore, any clients who had an initial score of 8 or higher were meeting caseness for that measure. Carrying on down the column, 72 of those 130 cases were scoring no longer at caseness when their last available GAD-7 measure was scored. They were therefore deemed to be ‘recovered’ according to GAD-7. The next item down on the column is ‘reliable recovery’. The ‘reliable change index’ for GAD-7 is where there has been a movement of 4 points or more. Therefore, a client who scored at ‘caseness’ to begin with will be deemed to have ‘reliably recovered’ if there has been an improvement in score of at least 4 points AND the final score is BELOW the clinical cut-off of 8 (a score of 7 or less). 71 of the 72 ‘recovered’ cases had ‘reliably recovered’.

Looking next at ‘reliable improvement’ this shows the number of clients (n=99) who improved by 4 points or more, regardless of where their original starting score may have been. This is important because a client may have improved considerably from a very high initial score but just not enough to make it to below the clinical cut-off.

Looking at PHQ-9, there were 153 clients with a 1st PHQ-9 measure completed and 142 clients who completed at least 1 additional PHQ-9 (attended at least 2 appointments).

Of the 142 who had a 1st and at least 1 other PHQ-9 115 of these were scoring at 'caseness', that is, at or above the clinical cut-off of the measure, which for PHQ-9 is a score of 10. Therefore, any clients who had an initial score of 10 or higher were meeting caseness for that measure. Carrying on down the column, 59 of those 115 cases were scoring no longer at caseness when their last available PHQ-9 measure was scored. They were therefore deemed to be 'recovered' according to PHQ-9. 'Reliable change' for PHQ-9 is where there has been a movement of 6 points or more. Therefore, a client who scored at 'caseness' to begin with will be deemed to have 'reliably recovered' if there has been an improvement in score of at least 6 points AND the final score is BELOW the clinical cut-off of 10 (a score of 9 or less). With the PHQ-9 this was 54 clients.

Looking next at 'reliable improvement' for PHQ-9 this shows the number of clients (78) who improved by 6 points or more, regardless of where their original starting score may have been.

Looking next at the data on the right of the table with the heading 'Both' one can see the combination of both measures. The common way for IAPT to report their results is to consider a client to be a 'case' when *either or both* measures are at or above their respective cut-offs. Therefore a client might score at caseness on GAD-7 but NOT on PHQ-9 or visa versa. However, to be deemed 'recovered' the client must score below 'caseness' on BOTH measures with their final scores. Looking at this combination one can see that 65 cases recovered (49.62% and 61 (46.56%) of those 65 made a reliable recovery. In the case of both measures the effect size is greater than 1.

These results compare favorably with published national IAPT data (NHS Digital, 2022) and with IAPT data specific to treatment of veterans (Clarkson, P., Giebel, C.M., Challis, D.,

Duthie, P., Barrett, A. and Lambert, H., 2016). Furthermore, it needs to be interpreted carefully in light of the fact that the attrition rates for the PTSD Resolution service are very low [152 of 174 completed referrals (87.35%) clients attended at least 2 treatment sessions and so would be defined as 'completers' by IAPT. Bearing in mind that the majority of veterans treated through PTSD Resolution self-refer, these high treatment retention figures are indicative of the acceptability of the treatment to the clients. The number of clients who drop out of IAPT services generally before getting to complete a 2nd measure is often very high [30 to 40% (Ghaemian, A., Ghomi, M., Wrightman, M., & Ellis-Nee, C., 2020; see also https://therapymeetsnumbers.com/iapt-2020-all-downhill-from-here/]. There may, of course, be many reasons for this. However, the stated target for reliable recovery rates for IAPT services is 50% (with many services falling short of this target, as explained in the previous citations). PTSD Resolution results achieve 47% reliable recovery rates where less than 13% of clients fail to 'complete' (as defined by IAPT).

Table 8 - Case report PTSD Resolution April 1, 2022 to March 31, 2023

GAD-7, PHQ-9 & PCL-5

	Primary		Secondary		Comparison	
Measure	GAD-7	%	PHQ-9-c	%	PCL-5	%
First Appt	155		153		150	
Later Appts	146	94.19	142	92.81	113	75.33
Cases	130	89.04	115	80.99	86	76.11
Recovered	72	55.38	59	51.3	54	62.79
Reliably Recovered	71	54.62	54	46.96	53	61.63
Reliably Improved	99	67.81	78	54.93	77	68.14
Effect Size						

Cohen's d	1.1728		1.0144		1.0762	
Hedges' g*	1.1698		1.0117		1.0726	

In table 8 above the data for GAD-7 and PHQ-9 remains unchanged from table 7. However, we have now included the PCL-5 for comparison. While the number of clients with a first available measure is around the same, the number of 'later appts' measures for PCL-5 is reduced (75% for PCL-5 compared with 94% for GAD-7 and 93% for PHQ-9). But, unlike the GAD-7 and PHQ-9 which are used as sessional measures (used at every session) the PCL-5 is typically administered at pre-treatment and post-treatment (1st and final session). If clients terminate prematurely, it then becomes very challenging to obtain a final PCL-5 score. Therefore, the clients who completed a PCL-5 at both the beginning and the end of treatment are much more likely to have arrived at an agreed planned ending. This explains the improved scores for the PCL-5 and highlights the fact that clients who stay in treatment to an agreed planned ending tend to have better outcomes.

PCL-5 and Post Traumatic Stress Disorder (PTSD)

While Human Givens therapists are not qualified to make a diagnosis of PTSD the PCL-5 self report measure provides a strong indication of probable PTSD. According to IAPT the adopted clinical cut-off score for the PCL-5 is 32. Scores at or above 32 are indicative of PTSD. Scores below 32 indicate the absence of PTSD.

Frequency table investigation of the PCL-5 scores of those clients who had a pre- and post-treatment PCL-5 score available (see table 8) revealed that 23.3% of clients scored 31 or less on the PCL-5 at their pre-treatment appointment. 76.7% of clients scored 32 or higher and more than 51.9% of the clients scored at 45 or higher. In other words, for more than 3

of 4 clients measured at pre-treatment with PCL-5 were indicating scores that would suggest probable PTSD.

For those clients with post-treatment PCL-5 scores available (which, as already explained, were the 75% of clients that arrived at an agreed planned ending with the therapist) 68.8% of clients scored 31 or less (compared to 23.3% pre-treatment) and just 31.2% of clients scored 32 or higher (compared to 76.7% pre-treatment), with less than 20% of the clients scored at 45 or higher (compared to 51.9% pre-treatment).

Table 9 - Case report PTSD Resolution April 1, 2022 to March 31, 2023

GAD-7, PHQ-9 & CORE-10

	Primary		Secondary		Comparison	
Measure	GAD-7	%	PHQ-9-c	%	CORE-10	%
First Appt	155		153		159	
Later Appts	146	94.19	142	92.81	146	91.82
Cases	130	89.04	115	80.99	140	95.89
Recovered	72	55.38	59	51.3	65	46.43
Reliably Recovered	71	54.62	54	46.96	60	42.86
Reliably Improved	99	67.81	78	54.93	96	65.75
Effect Size						
Cohen's d	1.1728		1.0144		1.1757	
Hedges' g*	1.1698		1.0117		1.1727	

In table 9, again, GAD-7 and PHQ-9 are unchanged. However here we can see the comparison of using CORE-10 on the same clients. CORE-10 is used on a sessional basis and so 146 (91.82%) of clients have at least one 2nd administration of the measure. 140 (95.89 %) of clients are 'cases' (at or above the clinical cut-off of 11) but a slightly smaller number of cases recover when compared to GAD-7 and PHQ-9 (42.86% for CORE-10 as opposed to

54.62%) for GAD-7 and 46.96% for PHQ-9). This is a product of the different psychometric characteristics of the measures, coupled with the fact that the CORE-10 is a broader instrument measuring distress more generally. However, and importantly, the reliable improvement rates for GAD-7 compared with CORE-10 are very close (67.81%) for the GAD-7 compared to 65.75% for CORE-10. Note also the similarity in effect size calculations, particularly between GAD-7 and CORE-10.

Table 10 - Case report PTSD Resolution April 1, 2022 to March 31, 2023

GAD-7, PHQ-9 & CORE-10 PLANNED ENDINGS ONLY

	Primary		Secondary		Comparison	
Measure	GAD-7	%	PHQ-9-c	%	CORE-10	%
First Appt	126		124		127	
Later Appts	125	99.21	121	97.58	126	99.21
Cases	109	87.2	100	82.64	121	96.03
Recovered	66	60.55	56	56	60	49.59
Reliably Recovered	66	60.55	51	51	56	46.28
Reliably Improved	88	70.4	70	57.85	88	69.84
Effect Size						
Cohen's d	1.289		1.1381		1.2995	
Hedges' g*	1.2851		1.1346		1.2956	

Table 10 shows results for agreed planned endings only. Comparing these results with table 7 one can see the impact of excluding those clients that do not arrive at an agreed ending, but terminate prematurely, for whatever reason.

Problems

Therapists ask the clients to identify their problems that bring them to treatment in their own words, how long they have been suffering with these problems for and what severity score they would give the problem(s) with 10 being worst and 0 best.

The comprehensive reporting of these results is beyond the scope of this initial paper but below in figure 2 is a word cloud based on word frequency for the client description of the 1st 2 problems they listed.

Figure 2 – Word cloud of frequently occurring words used by clients to describe their problems

Goals

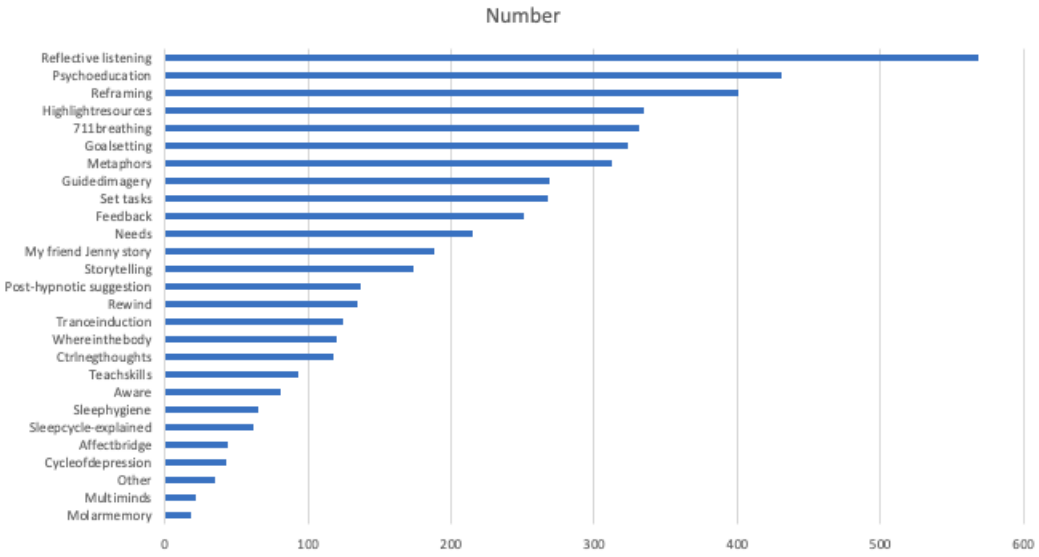
Similarly, where possible, therapists ask the clients to identify their goals for treatment in their own words, in other words, how will they judge the success or otherwise of the therapy, in terms of the achievement of those goals, where 0 scores not at all achieved and 10 scores fully achieved.

The comprehensive reporting of these results is beyond the scope of this initial paper but below in figure 3 is a word cloud based on word frequency for the client description of the 1st 2 goals they listed.

Figure 3 – Word cloud of frequently occurring words used by clients to describe their goals

Interventions

Figure 4 – Bar chart representing the frequency with which therapists used different interventions in their treatment sessions.



In Project-100, the therapists track the interventions that they utilise with their clients at each treatment session. The detailed analysis of these interventions, the frequency with which they are used and, for example, any association between their use and particular improvements on sessional measures, are beyond the scope of this paper but they will be addressed later. However, figure 4 provides some insight into the wide variety of interventions used by therapists in treatment.

Client feedback

Therapists routinely ask clients for formal feedback session by session, using different feedback instruments at different time-points. The results from feedback will be reported on in much more detail later but the results indicate a high and increasing level of satisfaction with the treatment as treatment progresses (average scores are 35.2/40 after the 1st appointment rising to 38.5/40 after the last appointment where scores are available.

Discussion

The intention with this report is to provide some initial results that could be made accessible to all interested parties concerned; therapists, clients, the charity, other organisations who may wish to refer to the charity and any other interested parties. The provision of evidence that can be deemed of acceptable quality to NICE has always been problematic for organisations like PTSD Resolution because RCTs require very high internal validity, treatments need to be manualised and adhered to and clients with any sort of confounding variables need to be excluded from the research. But PTSD Resolution accepts all referrals that make contact. The small numbers of clients who fail to progress with treatment do so of their own volition, 73% of completed referrals stay to an agreed planned ending.

Therapists are flexible and creative in their approach to treatment. Just brief attention to the interventions on figure 3 highlights the versatility and breadth of the sort of engagement with the clients, with 26 different interventions listed. This also illustrates the major challenge of investigation of treatment effects through RCTs, where therapists need to adhere to a strict manualised protocol in order to attempt to establish causality.

The publishing of the RWE framework by NICE in 2022 outlines a complementary approach for charities such as PTSD Resolution to provide evidence about treatment. Furthermore, producing results using the same measures that are used by IAPT services generally and IAPT veterans' services in particular allows the charity the ability to demonstrate at least equivalence to IAPT results. This is particularly encouraging when such high numbers of clients remain in treatment.

Focusing on measure choice, while CORE-10, PHQ-9, and GAD-7 are all commonly used outcome measures in psychological therapies, they differ in their specific purposes and

areas of focus. The CORE-10 measures overall psychological distress and functional impairment. It covers domains such as well-being, social functioning, and problems with day-to-day activities. The PHQ-9 measures the severity of depressive symptoms and is commonly used to screen for and monitor depression in clinical settings. The GAD-7 measures the severity of anxiety symptoms. In terms of similarities, all three measures are brief, self-administered questionnaires that can be completed quickly by patients. They are also all widely used in clinical and research settings to measure psychological distress and monitor treatment progress.

However, there are also some key differences between the measures. The CORE-10 is broader in scope than the PHQ-9 and GAD-7, as it covers a wider range of domains related to psychological distress and functioning. The PHQ-9 and GAD-7, on the other hand, are more specific in their focus on depressive and anxiety symptoms, respectively. The results in the Project-100 study suggest that all 3 measures have their strengths, and all are capable of successfully measuring change in treatment, with some minor variation between them. We believe that the burden of measurement should be kept to a minimum for clients and limited to what is most useful in treatment. The regular feedback from therapists is that the excessive burden of measurement on the client is often highlighted by clients as excessively demanding. The PCL-5 is particularly important with this client group because of the trauma that so many of them have been exposed to. Using idiographic measures around problems and goals helps therapist and client to maintain focus on what's important to the client in terms of the aims of treatment. It is to be hoped that there can be a rationalisation with respect to measurement as the knowledge gleaned from this real-world evidence based investigation is processed.

Limitations

This initial report on 12 months data collection lacks follow-up data. Clients are being followed up at 3, 6 and 12 months so these data will become available later. However, we felt it sensible to bring attention to these results as early as possible in order to inform all interested parties.

Acknowledgements

None of this would be possible without the effort and commitment of clients, therapists, administrators, researchers, and charity leaders and, most importantly, our grant funders, The Veterans Foundation (https://www.veteransfoundation.org.uk/)who help to finance all of the work involved. To all, our heartfelt thanks.

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