**Extended Data Table 1.** Summary of intervention development and co-production meetings and how these informed the PETAL therapy

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Meeting (date)** | **Attendees** | **Agenda items** | **Discussion** | **Outcomes reflected in the PETAL therapy and delivery** |
| Co-production meeting 1  (28-07-21) | Co-applicants & researchers: 7  Family carers: 6  Service users: 5 | Setting co-production ground rules  Programme updates  Discussions and reflections on:   * What should be in the manual? * How do we understand aggressive challenging behaviour? | The manual should have visual aids.  A person’s home environment may be triggering, and the therapy should be offered in-person in a ‘neutral’ clinical space.  Carers should be involved.  The number of sessions should be flexible to suit the individual and the therapy should be person-centred.  There needs to be an assessment of the person’s current needs undertaken first (including physical health, environment, unmet needs, history of therapy, etc.).  A communications/feelings passport can help people to communicate their needs to others and to better understand triggers for behaviour.  The reason for behaviour needs to be understood, including triggers, and setting events. It is also important to consider risk.  Strategies should focus on sensory processing. | Workbooks have been designed to provide visual aids for carers and service users.  There is flexibility for the location of therapy delivery.  Carers are involved in the therapy.  Some participants can have additional sessions if needed and the therapy can be tailored to the individual.  An assessment of the person’s needs is conducted in Module 1 ‘Getting to know the person’.  Communication passports have been included in Module 3 ‘Communication’.  Module 2 ‘Understanding aggressive challenging behaviour’ focuses on exploring triggers, setting events and risk management.  Module 5 ‘A calm environment’ includes a range of strategies aimed to reduce sensory stimulation and promote relaxation. |
| Co-production meeting 2  (23-08-21) | Co-applicants & researchers: 5  Family carers: 5  Service users: 2 | Summary of meeting 1  Discussions and reflections on:   * Therapy logic model * Mapping barriers and facilitators to the Theoretical Domains Framework based on the findings of the Rapid Realist Review and qualitative interviews with stakeholders and proposed solutions | More information should be included on physical health and relationship building between professionals and service users/carers.  Further information should be included in the logic model to highlight context and to re-frame the wording to avoid ‘blaming’ language.  Communication should be mentioned throughout the logic model.  Consider changes to the environment to improve aggressive challenging behaviour.  It is important to get to know the service user and for there to be collaborative working.  Setting realistic goals for meaningful activities if important, and financial constraints need to be considered.  Therapy is not always offered to service users due to complex needs and carers often are not supported enough either. | The logic model was updated to reflect these suggestions.  Environmental changes are explored through Module 2 ‘Understanding aggressive challenging behaviour’ and Module 5 ‘A calm environment’.  Time is spent in Module 1 ‘Getting to know the person’ to build relationships and to enable the therapist to understand more about the person’s needs.  Collaborative working between the caring network is explored in Module 3 ‘Communication’.  Setting realistic goals for meaningful activities and exploring financial barriers is included in Module 7 ‘Healthy habits.’  The aim of the therapy is to be tailored to individual needs and is designed for people with complex needs. The therapy is also for carers and includes a specific module to explore wellbeing, Module 6 ‘Carer wellbeing’. |
| Co-production meeting 3  (20-09-21) | Co-applicants & researchers: 4  Family carers: 7  Service users: 3 | Summary of meeting 2  Discussions and reflections on:   * Assessment of the person’s needs * How to support parents to support their child (what interventions could parents use to boost self-efficacy and improve wellbeing, and what support do people with learning disabilities want from their families?) | There should be a section in the manual for signposting to training and available support/services.  It should be emphasised that aggressive challenging behaviour is a result of unmet need.  The therapist should find out about the person’s likes and dislikes, behaviour, and its triggers and how to best communicate with them.  Therapists should be trained and should have experience working with people with intellectual disability.  Carers should be a part of the assessment.  Carers should be accepting of the person they care for and to communicate positively with them.  Carers need to have coping strategies and a network of support. Carers are often overburdened, and they need to feel supported from services.  People with intellectual disability need to be taken seriously and have their views listened to. | There is a section at the end of the manual and workbooks which signpost participants to additional resources and useful charities/services.  The message throughout the manual emphasises the issue of unmet need and a statement to convey and re-iterate this was written by family carers and has been included at the start of the manual.  Module 1 ‘Getting to know the person’ will assess the person’s likes/dislikes, communication style and behaviour.  Therapists will receive PETAL training and will be required to have some experience working with this population.  Carers will participate throughout the therapy and will have the opportunity to build communication skills during Module 3 ‘Communication’ and to explore their networks and wellbeing through Module 6 ‘Carer wellbeing’. Service users will explore assertive communication and how to effectively communicate with professionals in Module 3. |
| Co-production meeting 4 (22-10-21) | Co-applicants & researchers: 5  Family carers: 6  Service users: 3 | Summary of meeting 3  Discussions and reflections on:   * Awareness and understanding of aggressive challenging behaviour * Carer stress | The issue of support and training for carers was raised. There are two sources of carer stress, supporting the person and navigating the system and these should be acknowledged even if the intervention cannot directly address both. Carers need support to reduce stress as this can also negatively impact the service user. Carers can manage stress through support networks and by taking steps to improve wellbeing. Carers should be empathetic and should give the service user choices and independence where possible.  Important to be able to read the situation early and know the triggers and to learn how to implement strategies to reduce the occurrence of aggressive challenging behaviour. | Module 6 ‘Carer wellbeing’ addresses burden and ways to manage stress using the STOPP technique. Tips to improve wellbeing and exploring support networks are also included.  Ways to support the person and communicate in a positive and empathetic way, as well as including the person in decision making is included in Module 3 ‘’Communication’.  A tool to identify predictors of aggressive challenging behaviour has been added to Module 2 ‘Understanding aggressive challenging behaviour’ and carers are encouraged to complete this measure throughout the therapy to identify potential patterns. Antecedent-behaviour-consequence (ABC) charts have also been incorporated to support carers with identifying triggers. |
| Intervention Development  meeting 1  (29-10-21) | Co-applicants & researchers: 11 | Programme updates  Discussion and synthesis framework  Intervention content | It was highlighted that many of the barriers identified in the qualitative study were on the structural level, which will be challenging for the PETAL therapy to change unless there is co-operation from services.  Agreed carers should be involved and the role of carers should be clearly outlined. The proposed intervention modules were discussed. | Implementation is being continually reviewed as part of the study programme.  Carers are involved throughout the therapy. |
| Intervention Development  meeting 2  (08-12-21) | Co-applicants & researchers: 13 | Review of logic model  Programme updates – Rapid Realist Review programme theories  Review of possible materials to include and techniques to support behaviour change | The initial assessment of the person and their needs was deemed to be critical. This should include exploring comorbidities.  It was discussed whether there is enough overlap between the interventions for people with mild-moderate intellectual disability and people with severe intellectual disability.  The length of the intervention was discussed, and concerns were raised whether the therapy was long enough to support people with intellectual disability to understand what the therapy is about, build rapport with their therapist and to acknowledge how they feel about their behaviour.  Important to work within existing systems and relationships at the individual, family and systems level.  The idea of running some sessions in a group setting were discussed, although this was discounted due to worry over logistical issues. | Module 1 ‘Getting to know you’ has a comprehensive assessment of the person’s needs.  The therapy has been designed to be delivered to people with all levels of learning disability and can be delivered just to carers if needed. |
| Co-production meeting 5 (13-12-21) | Co-applicants & researchers: 13  Family carers: 4  Service users: 1 | Summary of meeting 4  Updates and recap on discussions at previous co-production meetings (including intervention pathways)  Discussion on assessment plan intervention content  Next steps | Therapist training needs to consider the differences between people and individuality. It was also suggested that therapist training include training with service users and carers.  People are less likely to display aggressive challenging behaviour when they are doing activities they enjoy.  Important to collect information on the person’s medical and behavioural history and communication style. A “getting to know you” session could be helpful.  The therapy should include communication tools and should explore ways of working together. | The therapist training includes pre-recorded videos of members of the service user and carer PPI groups to talk about different topics. 1-2 family carers are invited to attend the training sessions to provide opportunities for Q&As and to give carer perspectives.  Module 7 in the manual ‘Healthy habits’ explores meaningful activities and incorporating more of these into the person’s weekly routine to help reduce aggressive challenging behaviour.  Module 1 ‘Getting to know you’ is about building rapport and collecting information about the person’s needs and history.  Module 3 ‘Communication’ addresses how to communicate well with professionals and others in the caring network. |
| Co-production meeting 6  (16-02-22) | Co-applicants & researchers: 8  Family carers: 4 | Summary of meeting 5  Study update  Intervention content  Intervention delivery | Manual should be written in a more person-centred way. Some of the language used needs to be addressed.  It was decided that all modules should be delivered and should be tailored to suit the person’s needs. | A disclaimer was added at the start of the manual to discuss the use of terminology and language.  Guidance has been provided in the manual and training programme to support therapists to adapt the therapy where required. |
| Co-production meeting 7  (01-04-22) | Co-applicants & researchers: 11  Family carers: 3 | Summary of meeting 6  Overview of the manual (draft 2)  Implementation questions | SMART objectives should be included in the therapist training to help advise on how to personalise and tailor goals for the person. Written information on remaining issues could be provided to the person and their carer at the end of the therapy as it may be helpful to have evidence to help with seeking further support.  Workbooks need to be accessible and easy to follow. Therapists need to receive supervision and should access clinical supervision from the site.  It was suggested there should be some kind of formal structure in place to recruit and sign-off therapists to deliver the therapy. | SMART objectives and goal setting are covered during therapist training.  During the review sessions, the therapist explores any outstanding issues with the person and their carer and has been provided with template letters (for carers and an EasyRead version) to personalise for each person.  Workbooks have been developed that are accessible (and the person with learning disability version is in EasyRead). These have been reviewed by both respective PPI groups. Therapists are required to receive fortnightly clinical supervision from within their clinical team and research team group supervision every 6 weeks.  A written assessment has been included at the end of the therapist training sessions to assess key competencies.  Each therapist will receive individualised feedback and will then be signed off to deliver the therapy. |

**Extended Data Table 2**. PETAL intervention modules and how they map onto the Theoretical Domains Framework (TDF) domains and the workstream evidence

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Module** | **Section heading** | **TDF domains** *and constructs* (who for) | **Workstream evidence** | **Examples from PETAL therapist manual** |
| 1 – Getting to know the person | Brief assessment of needs | A. **Knowledge**  B. **Skills**  (therapist, carers) | * WS2 CRIS work – Psychiatric and medical comorbidities associated with poorer outcomes * WS3 Co-production meeting 1 (28-07-21) – an assessment of the current situation needs to be undertaken to understand the behaviour, environment, history and unmet needs | Exploring the person’s level of disability and communication styles, preferences, networks, behaviour, therapeutic history, physical and mental health (Pages 41-47, 52-58) (A)  Learning techniques to identify signs of pain (Pages 45, 56-57) (B) |
| **Social influences** – *social support*  (therapist-participants) | * WS1a Rapid Realist Review theme – Feeling valued, listened to and supported in therapy * WS1b Qualitative work theme – Developing rapport and relationships with service users and carers * WS3 Co-production meeting 2 (23-08-21) – service users should be able to develop a relationship with professionals | Advice on developing a therapeutic relationship (Pages 25-26) and spending time at the start of the session during the assessment of needs to get to know the person (e.g. their likes and dislikes) (Pages 42, 51-52) |
| Exploring readiness to change | A. **Beliefs about capabilities** – *self-efficacy, perceived competence*  B. **Beliefs about consequences** – *beliefs, outcome expectancies, attitudes*  C. **Optimism**  D. **Goals** – *goal setting, action planning*  (person with ID and carers) | * WS1b Qualitative work theme – Service user motivation as a facilitator of positive outcomes | Looking at participant’s capabilities, opportunities and motivation to make changes (A, B, C)  Exploring ways to promote behavioural change using a cost-benefit analysis (Pages 47, 58-60) (D) |
| 2 – What is aggressive challenging behaviour? | Understanding the causes of aggressive challenging behaviour | A. **Knowledge**  B. **Skills** – *skills development*  C. **Beliefs about consequences** *– outcome expectancies*  D. **Environmental context and resources** – *environmental stressors, person x environment interaction*  (person with ID and carers) | * WS1a Rapid Realist Review theme –building on existing carer skills * WS1b Qualitative work theme – Gaining a greater understanding of the condition * WS3 Co-production meeting 1 (28-07-21) – Need to understand behaviour, triggers, setting events, environment | Looking at the antecedent/triggers of behaviour (Pages 63-69, 75-78), behaviours (Pages 69, 78) and consequences (Pages 69-70, 78-79)  (A, C, D)  Learning to map out the antecedents, behaviours and consequences of aggressive challenging behaviour (ABC charts) (Pages 72, 82-84) (B) |
| Risk management | **Skills** – *competence, ability*  (person with ID and carers) | * WS1b Qualitative work theme – having tools to manage behaviour, improving the skills of staff * WS3 Co-production meeting 1 (28-07-21) – there needs to be an understanding of what to do to de-escalate situations | Teaching the three stages of de-escalation and how best to approach situations where aggressive challenging behaviour is escalating (Pages 70-71, 80-82) |
| 3 – Communication | Exploring different communication styles | A. **Knowledge**  B. **Skills** – *skills development, practice*  C. **Beliefs about capabilities** – *self-efficacy, self-confidence*  D. **Beliefs about consequences** – *outcome expectancies*  E. **Optimism**  F. **Memory, attention and decision processes**- *memory, decision making* (person with ID and carers) | * WS1a Rapid Realist Review theme – building on existing carer skills * WS1b Qualitative work theme –Effective communication of care and information sharing | Looking at the three types of communication (passive, aggressive and assertive) (A)  Exploring and practicing how to use the most effective form of communication (assertiveness) (B, C, D, E, F)  Ensuring participants feel more confident to convey their needs to others (Pages 85-86, 91-95) (C, D, E) |
| Communicating with professionals, with a person with a learning disability and with the caring network | A. **Knowledge**  B. **Skills** – *competence, ability*  C. **Social influences** –*intergroup conflict*  D. **Optimism**  E. **Environmental context and resources** – *organisational culture/climate*  (person with ID and carers) | * WS1a Rapid Realist Review theme – supporting communication between service users and family carers, and between service users, families and paid carers * WS1b Qualitative work theme –Effective communication of care and information sharing, multidisciplinary collaboration in care planning * WS3 Co-production meeting 2 (23-08-21) – effective communication and collaboration with all those involved in person’s care is essential | Providing information on using assertive communication to speak to professionals, about the STOMP initiative to stop the over-medication of people with ID and how to update summary care records (Pages 86, 95-96) (A)  Exploring how to best communicate with a person with ID (Pages 86-87, 96-97) and how carers can effectively communicate with the person’s caring network (Pages 87, 97-98) (B, C, D, E) |
| Communication passports | **Knowledge**  (carers) | * WS3 Co-production meeting 1 (28-07-21) – Some individuals may find that decisions are being made for them that they do not want. Therefore, a communication/feelings passport may be helpful to create for these individuals | Providing participants with the knowledge about what a communication passport is and why it can be helpful (Pages 87, 98-99) |
| 4 – Emotions | Introducing emotional regulation and recognising anger, Linking thoughts, feelings and behaviour | A. **Knowledge**  B. **Skills** – *skills development, practice*  (person with ID)  C. **Emotions** | * WS1a Rapid Realist Review theme – Emotion recognition, regulation and skill building for people with mild-moderate intellectual disability | Teaching how to recognise emotions  (A, B)  Making the link between thoughts, feelings and behaviour (Pages 101-102, 105-107) (A, B, C) |
| Trying a mindfulness activity | A. **Skills** – *skills development, practice*  B. **Beliefs about capabilities**- *self-confidence, self-efficacy, perceived behavioural control, empowerment*  (person with ID) | * WS1b Qualitative work theme – tools to manage behaviour | Learning and practicing a mindfulness activity to reduce negative emotions (Pages 102-103, 107-108) (A, B) |
| 5 – A calm environment | Distraction and calming activities | **Knowledge**  (person with ID and carers) | * WS3 Co-production meeting 4 (22-10-21) – using distraction is a helpful technique to reduce aggressive challenging behaviour | Providing an explanation for why these activities are important and can help to reduce aggressive challenging behaviour and gives examples (Pages 110, 114-115) |
| Relaxation and breathing techniques, using calm down tools | A. **Skills** – *skills development, practice*  B. **Beliefs about capabilities**- *self-confidence, self-efficacy, perceived behavioural control, empowerment*  C. **Environmental context resources** *– resources*  (person with ID and carers) | * WS1b Qualitative work themes – Person-centred support and environment, having tools to manage behaviour | Teaching and practicing relaxation activities (Pages 110-111, 115-117)  (A, B)  How to use calm down tools with a discussion on how to put this into practice and how to personalise this to the individual (Pages 111, 117-118)  (B, C) |
| 6 – Carer wellbeing | Improving wellbeing | A. **Knowledge**  B. **Skills** – *competence, ability*  C. **Beliefs about capabilities** – *self-efficacy, beliefs, empowerment*  D. **Emotions** – *stress, burn-out, negative affect*  (carers) | * WS3 Co-production meeting 4 (22-10-21) – carers may be experiencing stress and this is important to address to improve wellbeing | Providing tips to improve wellbeing and reduce stress/burnout (Pages 120-121, 125-127) (A, D)  Teaching the STOPP technique to help carers manage stress in the moment (Pages 121, 127-129) (B, C, D) |
| Support networks | **Social influences** – *social support*  (carers) | * WS3 Co-production meeting 3 (20-09-21) – carers should have several coping strategies and a network of support around them | Finding out about a carer’s support networks and signposting to local groups and resources that may be helpful (Pages 122,129) |
| 7 – Healthy habits | What is a healthy habit and why is it important? The BASE plan | **Knowledge**  (person with ID) | * WS1a Rapid Realist Review theme – meaningful activities for people with mild-severe intellectual disability | Looking at ways to improve wellbeing through healthy habits (being healthy, activities, socialising and enjoyment) (Pages 131-135, 140-144) |
| Looking at barriers to change | A. **Optimism**  B. **Intentions**- *stability of intentions*  C. **Beliefs about capabilities** – *self-confidence, perceived competence, self-efficacy, beliefs*  D. **Beliefs about consequences** – *beliefs, outcome expectancies*  E. **Environmental context and resources** – *resources/material resources, barriers and facilitators*  (person with ID) | * WS1b Qualitative work theme – Service user motivation as a facilitator of positive outcomes * WS3 Co-production meeting 1 (28-07-21) – financial and other barriers need to be considered that may prevent a service user engaging in meaningful activities | Looking at potential barriers in terms of the person’s capability, motivation and opportunity to incorporate meaningful activities and healthier habits into their lifestyle (Pages 136-137, 144-145)  (A, B, C, D, E) |
| Overarching for Modules 2-7 -  Setting of SMART objectives and home practice tasks | | A. **Goals** *– goal/target setting, action planning, implementation intention*  B. **Behavioural regulation** – *action planning, breaking habit, self-monitoring* | * WS1a Rapid Realist Review themes – personalising intervention-set objectives, facilitate practicing new skills * WS1b Qualitative work themes – involvement of service users in care planning, effective implementation of strategies * WS3 Co-production meeting 2 (23-08-21) – it is essential to set realistic goals | SMART objectives are set by participants with the guidance of the therapist at the end of every module and are tailored to the person (e.g. choosing a healthy habit to incorporate into their routine: pages 145-146) (A, B) |
| Overarching for Modules 2-7 -  Review of previous session and review of home practice tasks | | A. **Reinforcement** – *rewards, reinforcement*  B. **Behavioural regulation** – *action planning, breaking habit, self-monitoring*  C. **Memory, attention and decision processes** – *memory, attention, decision making*  (person with ID and carers) | * WS1a Rapid Realist Review themes – facilitate practicing new skills * WS1b Qualitative work themes – effective implementation of strategies * WS3 Co-production meeting 1 (28-07-21) – there needs to be reflection/debriefs so learning is taking place | Reviewing previous session content (e.g. Page 139) (C)  Goals/objectives are monitored and reviewed at the beginning of every session and participants receive feedback and encouragement for their progress, as well as support and advice to overcome any challenges (e.g. Pages 139-140) (A, B, C) |

**Note:** ID: Intellectual Disability

**Extended Data Table 3.** Implementation strategies following NPT

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **NPT Domain** | **Implementation Strategies by Implementation Agents** | | | | | |
| **Therapists** | **Supervisors** | **Referrers** | **Management** | **Patients** | **Carers** |
| **Coherence**- Does it makes sense? | Training  Information in Therapist Manual  Fidelity checklist | Initial training meeting  Will be provided with an information pack (includes workbook, manual, fidelity checklist, research documents) | Attendance at site initiation meetings  Team MDT meetings  Reminded during regular meetings by PI | Attendance at site initiation meetings  Discussion with research team – agree who takes on which roles | Explanation in session  Details in workbooks | Explanation in session  Details in workbooks |
| **Cognitive Participation -**  How do people engage? | Motivation and commitment encouraged during training (experts by experience delivering training and highlighting intervention importance through videos)  Documents and support available to facilitate delivery | Clear guidance on what is expected  Provide regular supervision | Guidance on what is required – referral form  Screening log to be completed | Discussion with research team – explained the potential importance of the intervention and guidance on what is required during site initiation visit and regular monitoring | Therapists encourage and provide optimism  Assessment of readiness for change and addressing barriers (Module 1)  Workbooks and home practice tasks to support  Offering personalisation and flexibility | Therapists encourage and provide optimism  Assessment of readiness for change and addressing barriers (Module 1)  Workbooks and home practice tasks to support  Offering personalisation and flexibility |
| **Collective Action -**  How do people work with intervention? | Receive appropriate training  Clinical supervision received regularly  Fidelity checklist | Meetings held at correct regularity | Regular review of caseloads  Actively referring patients | Management displays support in meetings and encourage referrers | Attend sessions as scheduled  Complete home practice tasks as planned | Attend sessions as scheduled  Complete home practice tasks as planned |
| **Reflexive Monitoring -**  How do people appraise intervention? | Can be appraised during clinical supervision  Fidelity checklist | Providing clinical supervision to discuss intervention |  |  | Weekly recap and review of home practice tasks  Review of what has been learnt and outstanding actions during final sessions | Weekly recap and review of home practice tasks  Review of what has been learnt and outstanding actions during final sessions |

| **Extended Data Table 4.** Baseline measures collected during the modelling study | |
| --- | --- |
| **Measure** | **Measure description** |
| Aberrant Behaviour Checklist – Irritability (ABC-I) – Primary outcome1, 2 | The irritability subscale includes 15 items scored on a 5-point likert scale to measure psychiatric symptomatology and behaviours in people with intellectual disabilities. 0 is ‘not at all a problem’ and 4 is ‘the problem is severe in degree’ (maximum score 60). |
| The Behaviour Problems Inventory for Individuals with Intellectual Disabilities - Short Form (BPI-S)3 | A 30-item rating instrument for adults with intellectual disabilities who display behaviours that challenge. It assesses frequency and severity and includes three subscales: Self-Injurious Behaviour, Stereotyped Behaviour, and Aggressive/Destructive Behaviour. Frequency is rated on a 5-point Likert scale ranging from 0 ‘never/no problem’ to 4 ‘hourly’. Self-injurious and aggressive behaviour severity is rated on a 3-point scale from 1 ‘mild’ to 3 ‘severe’. |
| Threshold Assessment Grid (TAG)4 | Measures the severity of a person’s mental health problems and includes 7 questions relating to risk, needs and disabilities. Domains are scored on a 4- or 5-point scale ranging from 0 ‘none’ to 3 ‘severe’ or 4 ‘very severe’ (maximum score 21 – 28). |
| Adaptive Behaviour Scale – Short Form (SABS)5 | 24 items to assess level of adaptive functioning in adults with intellectual disabilities living in community and residential settings. |
| Adult Social Care Outcomes Toolkit (ASCOT) proxy and carer6,7 | This toolkit measures a person’s social care-related quality of life. The proxy questionnaire is completed by family carers and has 8 items with 4 options ranging from ‘no control’ to ‘much control’. It asks the carer's opinion and how they think the person would rate themselves on several aspects of social care, including control over daily life, occupation, social participation, personal safety, personal hygiene, food and drink, accommodation cleanliness and comfort and dignity. The measure is preference weighted to reflect the relative importance of different aspects of outcome, and anchored, with final scores to 1 (the ideal state) and 0 (being dead), so it can be related to time. There is also a carer version for unpaid carers which has 7 items and is scored as 3 ‘ideal state’, 2 ‘no needs’, 1 ‘low level needs’ and 0 ‘high level needs’ to form an overall score between 0-21. |
| Warwick-Edinburgh Mental Well-Being Scale (WEMWBS)8 | A 14-item scale to explore feeling and functional aspects of carer mental wellbeing with 5 response categories, summed to provide a single score. Total score ranges from 14 to 70. |
| Difficult Behaviour Self-Efficacy Scale9 | A 5-item scale with a 7-point rating scale that looks at confidence, satisfaction, feelings of control and difficulty handling behaviours that challenge. The questionnaire rating scale ranges from 1 ‘not at all confident’ to 7 ‘very confident’ and scores are summed to create a total score. |
| The Moss Psychiatric Assessment Schedules (Moss-PAS (ID))10 | The Moss-PAS (ID) is a psychiatric assessment for people with an intellectual disability. It includes 66 items and generates a series of sub-scores on: depression (18 items), anxiety and phobias (8 items), mania (11 items), obsessive-compulsive disorder (4 items), psychosis (8 items), unspecified disorder (including dementia) (8 items), and autism (17 items). Items are rated on a 2- or 4-point scale, with a glossary detailing the coding of each sub score. |
| EuroQoL Five Dimensions – 3 Level (EQ-5D-3L)11 | A carer (proxy) measure to look at health-related quality of life and assesses health status within 5 dimensions: mobility, self-care, usual activities, pain/discomfort, anxiety/depression. Carers rate how they think the person with an intellectual disability would rate his/her own health-related quality of life on a 3-point scale of 1 ‘no problem’ to 3 ‘extremely/unable’. |
| EuroQoL Five Dimensions Learning Disability Scale (EQ-5D-LD)12 | This is a self-report adapted version of the health-related quality of life measure to assess health status within five dimensions for people with an intellectual disability: walking about, looking after myself, doing things I want to do, pain, sad and unhappy. These are scored on 3 levels ranging from 1 ‘can do’ to 3 ‘definitely cannot do’. |
| Client Service Receipt Inventory (CSRI)13 | A tool used to collect information on the range of services and supports adults with intellectual disability may use, including on accommodation, employment, service use history, hospitalisations for physical and mental ill health and medication. |
| Other therapies received (TAU for services) | Completed by the local clinical team |

1 Aman, M. G., Singh, N. N., Stewart, A. W., & Field, C. J. (1985). The aberrant behavior checklist: a behavior rating scale for the assessment of treatment effects. *American journal of mental deficiency*, *89*(5), 485–491.

2 Stoddard, J., Zik, J., Mazefsky, C. A., DeChant, B., & Gabriels, R. (2020). The Internal Structure of the Aberrant Behavior Checklist Irritability Subscale: Implications for Studies of Irritability in Treatment-Seeking Youth With Autism Spectrum Disorders. *Behavior therapy*, *51*(2), 310–319. <https://doi.org/10.1016/j.beth.2019.09.006>

3 Rojahn, J., Rowe, E. W., Sharber, A. C., Hastings, R., Matson, J. L., Didden, R., Kroes, D. B., & Dumont, E. L. (2012). The Behavior Problems Inventory-Short Form for individuals with intellectual disabilities: part I: development and provisional clinical reference data. *Journal of intellectual disability research: JIDR*, *56*(5), 527–545. <https://doi.org/10.1111/j.1365-2788.2011.01507.x>

4 Slade, M., Powell, R., Rosen, A., & Strathdee, G. (2000). Threshold Assessment Grid (TAG): the development of a valid and brief scale to assess the severity of mental illness. *Social psychiatry and psychiatric epidemiology*, *35*(2), 78–85. <https://doi.org/10.1007/s001270050011>

5 Hatton, C., Emerson, E., Robertson, J., Gregory, N., Kessissoglou, S., Perry, J., Felce, D., Lowe, K., Walsh, P. N., Linehan, C., & Hillery, J. (2001). The adaptive behavior scale-residential and community (part I): towards the development of a short form. *Research in developmental disabilities*, *22*(4), 273–288. <https://doi.org/10.1016/s0891-4222(01)00072-5>

6 Rand, S. E., Malley, J. N., Netten, A. P., & Forder, J. E. (2015). Factor structure and construct validity of the Adult Social Care Outcomes Toolkit for Carers (ASCOT-Carer). *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation*, *24*(11), 2601–2614. https://doi.org/10.1007/s11136-015-1011-x

7 Rand, S., Caiels, J., Collins, G., & Forder, J. (2017). Developing a proxy version of the Adult social care outcome toolkit (ASCOT). *Health and quality of life outcomes*, *15*(1), 108. <https://doi.org/10.1186/s12955-017-0682-0>

8 Stewart-Brown S, Janmohamed K. (2008). Warwick-Edinburgh mental well-being scale. User guide Version. 1(10.1037).

9 Hastings, R. P., & Brown, T. (2002). Behavior problems of children with autism, parental self-efficacy, and mental health. *American journal of mental retardation : AJMR*, *107*(3), 222–232. [https://doi.org/10.1352/0895-8017(2002)107<0222:BPOCWA>2.0.CO;2](https://doi.org/10.1352/0895-8017(2002)107%3c0222:BPOCWA%3e2.0.CO;2)

10 Prosser, H., Moss, S., Costello, H., Simpson, N., Patel, P., & Rowe, S. (1998). Reliability and validity of the Mini PAS-ADD for assessing psychiatric disorders in adults with intellectual disability. *Journal of intellectual disability research : JIDR*, *42 ( Pt 4)*, 264–272. <https://doi.org/10.1046/j.1365-2788.1998.00146.x>

11 Herdman, M., Gudex, C., Lloyd, A., Janssen, M., Kind, P., Parkin, D., Bonsel, G., & Badia, X. (2011). Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation*, *20*(10), 1727–1736. <https://doi.org/10.1007/s11136-011-9903-x>

12 O'Dwyer, J., Meads, D., Bryant, L., Kind, P., & Hulme, C. (2020). *Estimating health-related quality of life for adults with learning disabilities*. Quality of Life Research; Springer Van Godewijckstraat 30, 3311 GZ Dordrecht, Netherlands.

13 Beecham, J., & Knapp, M. (1995). The client service receipt inventory. Discussion Paper 1492. Personal Social Services Research Unit, University of …,<https://www.pssru.ac.uk/csri/client-service-receipt-inventory/>

|  |  |  |
| --- | --- | --- |
| **Extended Data Table 5.** Findings from the modelling study and changes made to the PETAL therapy | |  |
| **Findings from modelling** | **Source and example quote (if relevant)** | **Change made for the PETAL therapy to be used in the main trial** |
| Carers and therapists highlighted  that some of the language in the PETAL therapy was not accessible enough for people with intellectual disabilities | Qualitative interviews (coherence - individual specification)  *“The format or the content or the language maybe being less accessible to people with more moderate learning disabilities” (Supervisor 1)* | The wording and language of the manual, workbooks and module scripts were revised to improve accessibility and to ensure uniformity in the terminology used |
| Not all the content in the PETAL therapy was relevant for every person | Qualitative interviews (reflexive monitoring - individual appraisal)  *“She wouldn't let you touch her or do exercises or breathing techniques or anything like that, so again, strategies like that weren't beneficial to the client” (Carer 8)*  *“it's always good to have different tools to see which ones fit for people” (Service Manager 1)* | Further guidance provided in the therapist training programme on how to adapt the content based on the person’s needs and to try different elements and then focus and reinforce those that work and are effective |
| Sometimes the person with an intellectual disability or the carer struggled to engage | Fidelity observations and qualitative interviews  (collective action - interactional workability)  *“He was just like `I don't want to do this anymore, and that's when we cut it down from an hour to about 15 minutes we'd see him, the rest of the session [therapist] and I would talk about it and figure out what the best, what was helpful for him and what wasn't.” (Carer 2)*  *We worked on the communication plan, you know, some of the emotional things. Some of them, the service user didn't want to do. So, we had to try and persuade him to do it. And he did, some of them, but not a lot of them. (Carer 6)* | Providing further guidance in the therapist training programme on how to adapt sessions and how to engage participants |
| Challenges with carer continuity between sessions and when completing home practice tasks | Qualitative interviews (collective action - interactional workability)  *“To be frank, we didn't do, cause if he didn’t do it, it was a bit difficult to get everybody to get on board with it, you know. I mean without me being there all the time” (Carer 6)* | Addition of carer crib sheets and highlighting this in the training |
| Therapist confusion about how much to personalise and adapt session content | Qualitative interviews (collective action - interactional workability)  *“And I think the main thing that kind of repeatedly came up that we had, I think would have been helpful to think about more at the beginning, was how much the person, the therapist, can adapt the manual to the individual. And how much it needs to remain, kind of fidelity to the manual” (Supervisor 1)* | Providing further guidance in the therapist training programme on how to adapt sessions and the scope for this |
| Therapists not appropriately reviewing previous sessions and re-capping home practice tasks. Carers felt they needed more opportunities to self-reflect on what they had learnt | Fidelity observations and qualitative interviews (reflexive monitoring - reconfiguration)  *“We need to be able to assess ourselves, maybe after every session… the questions that I think we should be asking should be – “What has the service user gained, and what have the carers gained?” (Carer 7)* | Additional information added to the manual to encourage therapists to check in with participants at the end of sessions to check learning. Further emphasis added in the therapist training programme to ensure therapists review and sufficiently re-cap previous sessions and home practice tasks |
| Therapists not setting home practice tasks using SMART objectives | Fidelity observations | Further emphasis on this included within the therapist training programme and role plays involving the setting of SMART objectives included as part of the therapist assessment |
| Therapists reported additional materials and visuals would be beneficial to support the person with an intellectual disability during sessions | Qualitative interviews (reflexive monitoring - reconfiguration)  *“Having a bit of a print out of the modules, you know that the participant could put up on their wall and like tick off each module as they do it again just to see where they are.” (Therapist 2)* | Crib sheets for the person with an intellectual disability were developed and uploaded to the therapist resource website |
| Therapists reported that conversations about the person’s behaviour and behavioural triggers were usually had with the carer and talking about someone’s behaviour in front of them did not seem appropriate and in some cases caused upset and distress | Qualitative interviews (reflexive monitoring - individual appraisal)  *“Module 2, that was a difficult module. The content was uh, so long. It was quite in depth. It's generally an intense module….it was quite triggering for us actually” (Therapist 5)* | The module on understanding aggressive challenging behaviour was changed to be delivered to carers only |
| Delivering the therapy to a triad was more challenging than dyads and impacted the ability of people with an intellectual disability to contribute during sessions | Fidelity observations | The inclusion of triads within PETAL therapy sessions was removed, although a second carer is now invited to attend review sessions if appropriate |