The Thalidomide Trust

PAIN MANAGEMENT – RESEARCH BRIEF

1. Introduction to the Thalidomide Trust

The sedative drug, thalidomide, was approved and licensed for distribution in the UK in April 1958, primarily under the brand name Distaval, and was withdrawn in December 1961 when it was found to have caused serious birth defects in babies born to women who ingested the drug during the first trimester of their pregnancy.

Thalidomide affected the development of the fetus in different ways and the resulting disabilities include damage to the upper and lower limbs, musculoskeletal problems, facial damage, sensory impairment (including vision and hearing) and damage to internal organs. A small number of individuals were also born with cognitive impairments.

The Thalidomide Trust, a UK registered charity was established in 1973 to provide assistance and support to individuals living with thalidomide damage. The majority of their beneficiaries are now in their early 60s and most are feeling the impact of using their bodies in ways they were never designed for. In addition, as they age, beneficiaries are experiencing a wide range of age-related health problems that are exacerbated by their original thalidomide damage.

The Thalidomide Trust meets these increasingly complex needs through the provision of financial support and a range of information, advice and advocacy services. To underpin this we gather evidence on the needs and experience of our beneficiaries and undertake more detailed research on topics that are of greatest relevance to them.

The Thalidomide Trust's **Vision ….** *is that each and every beneficiary of the Trust has access to the resources and support they need to live their best life for the longest time.*

2. Thalidomide Damage and Pain

Evidence shows that our beneficiaries experience significantly worse physical and mental health than the general population of the same age. Our data show that there is a higher prevalence of all those categories of ill health measured by the Health Survey for England (HSE) compared with non-thalidomide age matched population. Pain is the health issue which is most reported by beneficiaries - with 91% reporting pain in four different sites, frequently experienced on a daily basis. This seriously impacts their quality of life and ability to remain fully independent and suggests that beneficiaries are enduring significant discomfort in multiple locations of their body every day.

There are multiple reasons why someone with thalidomide damage will have pain levels greater than in the general population:

- Joints damaged by thalidomide in utero are more prone to arthritis
- Excessive strain is put on other joints which are used to compensate for limbs damaged by thalidomide

- Functional pain occurs due to abnormal alignment of joints
- Compression neuropathies are common
- Muscle tension and spasm occur due to abnormal posture.

Research conducted by the Thalidomide Trust in partnership with the University of Modena has also suggested the possibility of an underlying generalised neuropathy associated with thalidomide damage.
https://journals.plos.org/plosone/article?id=10.1371%2Fjournal.pone.0152902

This is borne by more than half of beneficiaries reporting pins and needles and/or numbness.

More recently, research carried out with thalidomide survivors in Germany has concluded that people with thalidomide damage frequently suffer from a separate pain disorder which can be seen as secondary thalidomide-induced damage and which requires specialised and personalised multimodal pain management https://pubmed.ncbi.nlm.nih.gov/33915582/.

There are a number of barriers to beneficiaries seeking help and treatment for their pain, including a reluctance to take tablets due to their formative experience with thalidomide, poor experiences of multiple interventions and surgeries as children, and difficult experiences with health care professionals who do not understand their unique and complex needs. Our experience indicates that these barriers can prevent beneficiaries from accessing standard NHS pain management services and that standard pain treatment pathways are often inappropriate for the beneficiary group.

For this unique beneficiary group with such a significant extent and experience of pain the lack of an effective bespoke approach to pain management is a significant gap and the need to develop one is paramount

3. Aims of the study

- To define the experience of pain suffered by beneficiaries.
- To identify and describe best practice approaches to pain management and their likely efficacy for the beneficiary group.
- To define and describe an effective pain management pathway that reflects and will meet the unique needs of beneficiaries of the Thalidomide Trust.

4. Overall design - Scope and Stages of Project

The scope of this project includes the following stages:

4.1 Undertake an analysis of the extent and characteristics of pain in the beneficiary group - using existing quantitative data gathered by the Trust.

In reviewing these data, we would expect the researchers to identify any information gaps and make recommendations to address these gaps.

4.2 An investigation of the beneficiary experience of pain and managing pain. What interventions are used, or tried in the past, and the nature, extent, and effectiveness of these. To include an understanding of the experience of accessing NHS or private pain interventions, from GP to pain clinics.

This requires new primary research with the beneficiary group to provide an in-depth exploration of how beneficiaries currently experience and manage their pain. The outcome would be an analysis of beneficiary experience and requirements that can be mapped against the analysis at stage 3.

4.3 An investigation of models of pain management, the current pain interventions/ services available - on the NHS and privately - including best practice, evidence of effectiveness, availability, waiting lists etc.

The outcome would be a review of current pain management pathways and interventions available in the NHS and private sectors, as well as emerging and new approaches to managing pain and should include factors such as costs of models, the evidence base of their effectiveness, their likely availability and accessibility and their patient acceptability.

4.4 Gap analysis of the investigations at stages 2 and 3 and the development of recommendations to the Trust to address the gaps and define a pathway to meet beneficiary needs. Recommendations could include:

- Services/programmes/advice delivered by the Trust
- Specialist clinical services commissioned by the Trust.
- Recommendations to clinicians (e.g. GPs/nurses) available from Trust website

5. Timescales

We expect the research to be completed within 12 months of the agreed start date.

6. Application Process

This brief should be considered an invitation to tender. Expressions of interest and any questions should be submitted to katy.sagoe@thalidomidetrust.org

Bids to undertake this work must be received by **12 noon on 17 April 2023** and must be submitted using the application form attached at pages 5 – 10 to katy.sagoe@thalidomidetrust.org

Shortlisting will take place before the end of April and applicants will be notified as soon as possible if they have been shortlisted for interview.

Interviews will take place on **11 May 2023**

7. Selection Criteria

Applications will be assessed by how clearly they demonstrate –

- insight into the issues caused by thalidomide damage,
- experience in the field of pain research including pain management,
- commitment to working in partnership with research participants,
- understanding of ethical issues posed by planned research,
- value for money,
- commitment to deliverables of relevance to the Trust's beneficiaries,

8. Funding

The funding available for this study is up to £75,000 and this is expected to include salary and on-costs of the researcher, together with travel, consumables and the costs of beneficiary research. As a charity, the Trust will not fund FEC/overheads.

9. Ethics

The researcher is expected to ensure all necessary and appropriate approvals are in place for each stage of the study.

10. Data Management

The Thalidomide Trust will make available access to data and beneficiaries as required by the researcher, subject to the terms of a data sharing agreement between the Trust and the research team, and which fully complies with the requirements of GDPR.

11. Publication

The Trust encourages publications in appropriate academic journals, subject to approval by the Trust

12. Further Information

Any questions or requests for further information should be directed to Katy Sagoe, Director of Health & Wellbeing at katy.sagoe@thalidomidetrust.org

The research project will be overseen and supported by the Research Committee of the Thalidomide Trust, which includes beneficiary representatives.

More information about the Thalidomide Trust can be found on our website –

https://www.thalidomidetrust.org/

The Thalidomide Trust

Thalidomide Trust - Research Application Form

PAIN MANAGEMENT INVESTIGATION

The Award will be up to £75k directly incurred costs only, for up to 12 months. Projects seeking lower amounts will be considered. This form should be completed by the Principal Investigator.

The following criteria will be considered during the evaluation of applications:

- Evidence of insight into the issues caused by thalidomide damage,
- Experience in the field of pain research, including pain management,
- Commitment to working in partnership with research participants,
- Understanding of ethical issues posed by planned research,
- Value for money,
- Commitment to deliverables of relevance to the Trust's beneficiaries

The deadline for submission of completed applications is 12pm, Monday 17 April 2023.

Shortlisting will take place and applicants will be notified as soon as possible if they have been shortlisted for interview before the end of April 2023.

Interviews will take place on **11 May 2023**

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Section 1: Project Summary

1.1 Title (max 150 characters) *Please provide a title suitable for inclusion in open access forums*

1.2 Technical Summary (max 400 words)

1.3 Project Duration and Cost	
Proposed start date	
Proposed duration of award (Up to 12 months)	
Funding requested (up to £75K directly incurred costs only - lower amounts will be considered**)**	

Section 2: Investigator Details

2.1 Principal Investigator	
Name	
Post Held	
Department	
Email and Telephone No.	

2.2 Co-Investigators	
Name	**Institute/Organisation/Company**

Section 3: Approach

3.1 Project Proposal – please set out your approach to each stage (max word count 2000 word)

3.2 What is your proposed approach to working in partnership with research participants?

Section 4: Experience

4.1 What is the supporting evidence of your experience in the field of pain research and pain management?

4.2 Please provide up to 5 references of your previous work in this field

Section 5: Deliverability

5.1 Outline the key deliverables for this project.

5.1 Outline the work plan, including milestones and success criteria for this project. A Gantt chart summarising the key activities and timelines should be included as an additional data attachment

5.2 Justification of resources requested in the budget

5.3 Describe your plan to disseminate the outcomes of the research

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Section 6: Additional Information

6.1a Ethical Approval.
Does the project require ethical approval? **Yes** ☐ **No** ☐
6.1b What is your proposed approach to ensuring appropriate ethics approvals are in place for this project?

6.2a Staff recruitment.
Does the project require the recruitment of any staff? **Yes** ☐ **No** ☐
6.2b What is your proposed recruitment process and timeline?

6.3 Please include any other relevant information that you feel will help support your application (max 200 words)

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Section 7: Budget and Signature Form

Details of support requested in Section 1.3 above:

BUDGET:			
Departmental Finance Contact(s)			
Budget Organisation	**Description** *(please provide the Finance contact details for the PI and <u>every</u> other budget holder)*		
Type	**Description** *(please provide reasonable detail of cost components)*		
Directly Incurred Costs			
Staff Costs		£	£
Equipment		£	£
Consumables		£	£
Other		£	£
Directly Allocated Costs			
Staff Costs		£	
Indirect costs		£	
TOTAL		**£**	**£**

SIGNATURES:		
PRINCIPAL INVESTIGATOR I declare that the information given on this form is complete and correct.		
Name (print):	Signature:	Date: