

# Understanding and supporting families with TSC-Associated Neuropsychiatric Disorders (TAND) in India – Study Protocol

Shoba Srivastava<sup>1</sup>, Nola Chambers<sup>1</sup>, Pradnya Gadgil<sup>2</sup>, Anna Jansen<sup>3</sup> & Petrus J de Vries<sup>1</sup>

1 Division of Child & Adolescent Psychiatry, University of Cape Town, South Africa; 2 Department of Neurosciences, Society for the Rehabilitation of Crippled Children (SRCC) Hospital; 3 Vrije Universiteit Brussel



✉ shoba\_srivastava@yahoo.co.in



## INTRODUCTION

- ❖ Tuberous Sclerosis Complex (TSC) is a rare genetic disease characterized by multi-system physical manifestations and hard-to-treat epilepsy
- ❖ TSC is also associated with a wide range of neuropsychiatric difficulties, referred to as TSC-associated neuropsychiatric disorders (TAND)
- ❖ TAND difficulties are very variable across individuals with TSC, but research has identified seven natural TAND clusters, including an autism-like, dysregulated behaviour, mood/anxiety, overactive/impulsive, neuropsychological, scholastic and eat/sleep cluster
- ❖ TAND are generally under-diagnosed and under-treated, yet are associated with a significant burden on families

## TAND in INDIA

- ❖ India is a large diverse country with a population of 1.4 billion and probably has at least 230,000 people with TSC
- ❖ The first formal TSC parent support group was created in 2018 (group of 200 families). This led to the 1<sup>st</sup> TSC clinic in Mumbai in 2018, followed by 2 more clinics in New Delhi and Hyderabad, all in urban areas
- ❖ It is likely that TSC and TAND are not recognized sufficiently in India, particularly in rural areas
- ❖ Little is known about TAND in India. A recent scoping review found only nine published TAND-related peer-reviewed publications from India, all case reports (Vanclouster et al., 2022), suggesting a significant knowledge gap

## THE TANDEM PROJECT

- ❖ The TANDEM Project is an international multi-disciplinary mobile-health project launched in 2019 carried out by a 26-member consortium of researchers, clinicians and TSC family members
- ❖ The project led to the generation of a self-report, quantified TAND Checklist (TAND-SQ) embedded into a mobile application, the 'TAND Toolkit App' (Figure 1) linked to a set of consensus clinical recommendations and practical toolkit to help families and individuals address their TAND difficulties
- ❖ The TANDEM project also described a new 'wraparound' psychosocial cluster, which emphasized the importance of caring for caregivers. To date, no caregiver wellbeing programmes have been evaluated in the TSC community
- ❖ The TAND Toolkit app has had feasibility evaluation by families in the USA and Belgium. To date, it has not been evaluated in any low/middle-income country, where it may be an extremely useful tool to reach and empower families

**Table 1:** All studies on TAND in India identified in a comprehensive scoping review (see Vanclouster et al., 2022 for details)

Study Title	Year	TAND Cluster
Mania in a Five-Year-Old with Tuberous Sclerosis	1989	Mood/Anxiety
Childhood Autism in Tuberous Sclerosis	1998	Autism-like
Psychological intervention in Tuberous Sclerosis: A case report	2002	Dysregulated behaviour
Bipolar disorder associated with Tuberous Sclerosis: Chance association or aetiological relationship?	2006	Mood/Anxiety
Correlation of autism with temporal tubers Tuberous Sclerosis Complex	2008	Autism-like
Autism and mental retardation with convulsion in Tuberous Sclerosis: a case report	2012	Autism-like
Atypical presentation of Tuberous Sclerosis and obsessive-compulsive disorder in an adult male	2012	Mood/Anxiety
Tuberous Sclerosis presenting as psychosis in adolescent patient	2014	Dysregulated behaviour
Successful treatment of Tuberous Sclerosis with psychosis and obsessive-compulsive disorder: A case report	2015	Mood/Anxiety

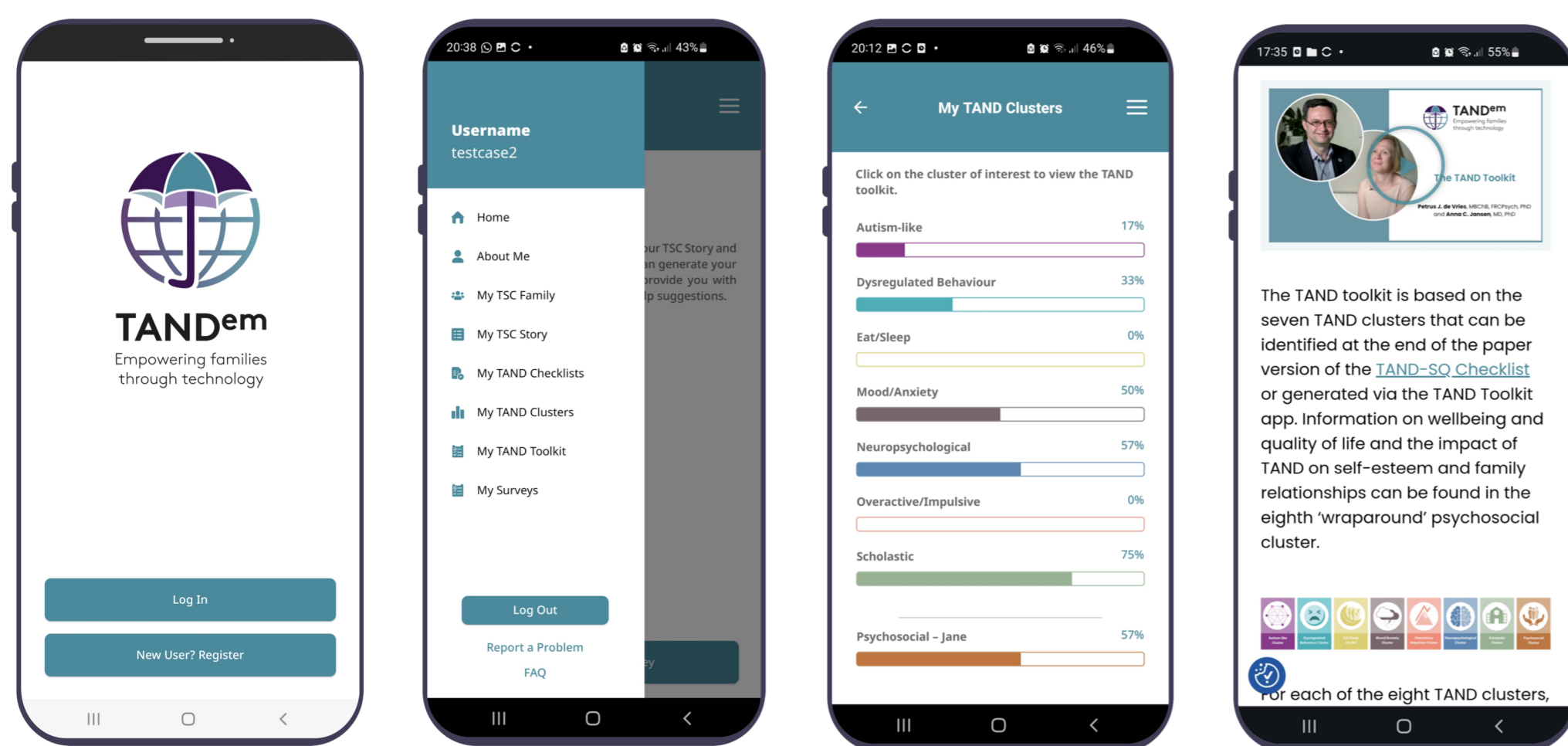


Figure 1. TAND Toolkit app

## STUDY AIMS

The overall goal of this study is to understand and describe the TAND landscape in India and to evaluate two ways to help families and individuals manage TAND. The study has three aims:

- Aim 1:** Explore the perspectives of Indian families and professionals regarding TAND
- Aim 2:** Evaluate the feasibility and acceptability of the TAND-SQ Checklist and the TAND app in India
- Aim 3:** Evaluate the feasibility, acceptability, and efficacy of a brief web-based caregiver wellbeing programme for Indian caregivers. This three-session programme is based on Acceptance and Commitment Therapy (ACT), a well-researched method for helping individuals cope better in situations that are not likely to change

## STUDY DESIGN AND METHODS

This study will use mixed methods to achieve the three aims:

- Aim 1:** A) Focus group discussions (FGDs) will be carried out with families regarding TAND issues (30 families).  
B) Semi-structured individual interviews (SSIs) will be carried out with professionals and will include questions on TAND treatment (6-10 professionals).
- Aim 2:** A) 50 Families will be invited to download and register on the TAND app, fill out the TAND-SQ Checklist and explore the Toolkit resources. All families will be asked to complete a Toolkit feasibility form and an app feedback form that contains both closed- and open-ended questions.  
B) FGDs will be conducted with a subset of families to evaluate (i) feasibility of the TAND-SQ Checklist, (ii) ease of usage of the app, and (iii) cultural appropriateness of the app.
- Aim 3:** A) A quasi-experimental wait-list crossover design will be used to implement the caregiver well-being intervention to two groups of caregivers. Participants will complete pre-post measures of well-being to assess efficacy.  
B) At the end of the intervention families will be invited to FGDs to share their perspectives about the feasibility, acceptability and cultural appropriateness of the programme

All quantitative data will be analyzed using descriptive statistics. Pre/post analysis will use non-parametric Wilcoxon signed ranks test (SPSS). Qualitative data will be analyzed using thematic analysis with the NVivo software

## STUDY OUTCOMES

- ❖ Improve understanding of the TAND needs and priorities of Indian families
- ❖ Provide evidence of the feasibility of the TAND Toolkit app (TAND-SQ and toolkit) in the Indian context
- ❖ Inform the appropriateness, acceptability, and feasibility of the caregiver wellbeing programme for TSC caregivers in India

## REFERENCES

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