Summary of the Clinical Research Report

Title: Clinical Research on the Effectiveness and Safety of the Ultrasonic Head Stimulation Device Ultra-Ma for Patients Diagnosed with Lewy Body Dementia

Date of Creation: October 21, 2021

Objective:

The primary aim of this clinical research was to evaluate the effectiveness and safety of the Ultra-Ma device in improving cognitive function and managing behavioral and psychological symptoms associated with dementia (BPSD) in patients diagnosed with Lewy body dementia.

Research Device:

- **Device Name:** Ultra-Ma (Development Code: KMY-01)
- **Provider:** Ueyama Manufacturing Co., Ltd.

Study Design:

- **Type:** Multicenter, single-blind, interventional study
- **Participants:** Patients clinically diagnosed with mild to moderate Lewy body dementia exhibiting BPSD

Key Personnel:

- **Principal Investigator:** Yuta Manabe, Kanagawa Dental University Hospital
- **Facilities:** Kanagawa Dental University Hospital and its affiliated clinics

Ethics and Registration:

- Approved by the KKR Toranomon Hospital Clinical Research Review Board
- Registered under jRCTs032190012

Methodology:

1. **Participant Criteria:**
   - **Inclusion**: Patients aged 60-90 with Lewy body dementia diagnosis, having BPSD, capable of daily monitoring, and with a caregiver.
   - **Exclusion:** Patients with other types of dementia, severe musculoskeletal disorders, substance dependency, significant neurological conditions, or those using incompatible medical devices.

2. **Intervention:**
   - **Duration:** 12 weeks (4 weeks sham stimulation, 8 weeks actual stimulation)
   - **Frequency:** Twice daily (20 minutes each session)
   - **Stimulus:** Ultrasonic waves at 30 kHz with specific intensity levels for sham and actual stimulation

3. Evaluation:
   - **Primary Outcomes:** Changes in BPSD (NPI-Q) and cognitive function (MMSE)
   - **Secondary Outcomes:** Caregiver burden (Zarit-8), motor function (MDS UPDRSⅢ), mild cognitive impairment (MoCA-J), cognitive function fluctuation (CFI), and daily living activities (BI)
   - **Safety Assessments:** Monitoring adverse events and device malfunction

Results:
   - **Effectiveness:** Improvements in BPSD and cognitive functions were observed.
   - **Safety:** No significant adverse events related to the device were reported.

Conclusion:
The Ultra-Ma device demonstrated potential effectiveness in improving cognitive functions and managing BPSD in patients with Lewy body dementia, with a favorable safety profile. Further studies and continuous monitoring are recommended to validate these findings.

This summary condenses the key aspects of the clinical research report, highlighting the objective, methodology, results, and conclusions.