Writing A Research Protocol for A Prospective Clinical Trial In The Treatment Of Hypertrophic Scars

Christine Reichard

Sigrid A. Blome-Eberwein MD

Writing a clinical research protocol for a prospective clinical trial in the treatment of hypertrophic scars

Christine Reichard, Sigrid Blome-Eberwein MD
Lehigh Valley Health Network, Allentown, Pennsylvania

INTRODUCTION

- Both fractional CO_2 laser therapy and microneedling have shown clinical efficacy in recent decades
- In 2016, our burn center published a study that showed significant scar quality improvement using a 2.0 mm fractional CO_2 laser.
- Penetration depth of scar treatment is not yet understood. Laser treatments may go up to 4.0 mm, but no clinical studies have yet investigated a significant correlation between treatment depth and scar quality
- Physicians offer scar treatment with incessant goal to improve scar quality for patients whilst only utilizing necessary techniques.

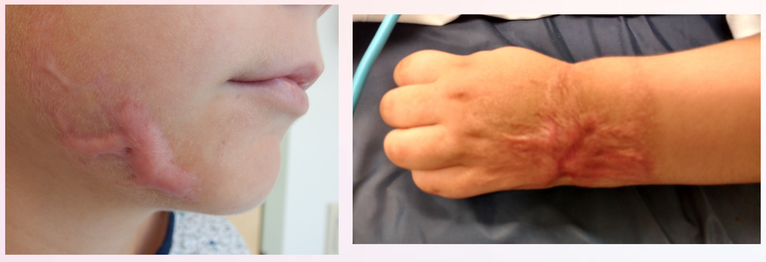

Figure 1A and 1B. Hypertrophic scarring observed by the Burn Recovery Center.

PURPOSE

- To investigate relation between penetration depth and scar quality improvement, a clinical trial must be conducted. Three treatment modalities are proposed to investigate: 2.0 mm laser therapy, 3.0 mm microneedling, and 4.0 mm laser therapy.
- Writing a protocol is the necessary first step to building an efficient study: Methods and treatment are clearly outlined while ensuring patient safety.
- Protocol construction allows for further movement in the study, such as consent form, budget, and codebook creation.

METHODS

- Primary literature review focused on scar treatment, depth, and measurement device functionality was reviewed and gathered.
- Research question, “Does depth matter?” was transformed into study hypothesis: “Penetration depth of fractional injury to scar does not make a difference in final improvement outcome as measured by the Patient and Observer Scar Assessment Scale (POSAS) and objective measurements of scar physiology.”
- The protocol was constructed: Hypotheses, study design, patient enrollment, treatment procedure, measurement modalities and collection, and statistical analysis were detailed.
- Departmental protocol review provided insight into the practicality for study details and investigator contribution.
- Further projects in the study found their foundation in the protocol. The consent form was composed for patients to understand their possible enrollment. A budget was constructed based on supply and labor costs. A data collection REDCap codebook was created for statistical analysis.
- Biostatisticians provided a NORI feasibility assessment to ensure that the study and its results were practical and achievable. Through collaboration, the protocol and codebook were discussed and approved. A sample size analysis was provided. Funding was applied for based on the budget.
- The protocol, codebook, and consent form will be electronically submitted to the IRB for review and approval, indicating compliance with the ethical standards of human research and institutional resources.

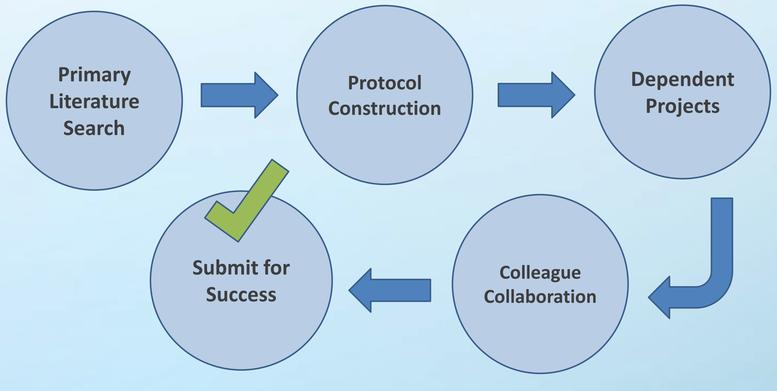

Figure 2. Sequence of primary steps for clinical trial study proposition.

RESULTS

- The project resulted in a successful study protocol.
- A foundational guide is provided for each step of the trial process, such as patient enrollment, clinical treatment, data recording, and statistical analysis.

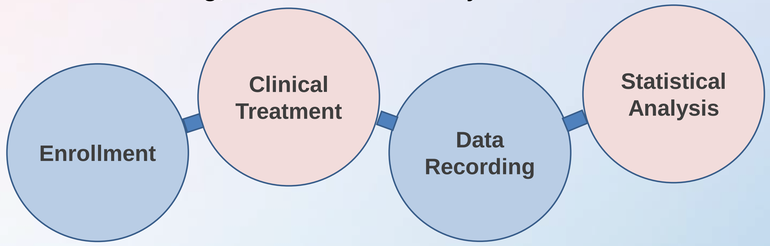

Figure 3. Approximate primary and linked steps of clinical trial process.

CONCLUSION

- Written protocol provides facilitation of future study
- The protocol, budget, consent form, and codebook will be utilized consequently during the clinical trial and analysis.
- Penetration depth investigation will benefit physicians by providing further understanding of the scar treatment. Patients will benefit by receiving scar treatment with significant improvement.
- A thorough understanding of the research approval process was gained, as the necessities of constructing a clinical study were experienced firsthand. Primary literature review, detailed document and codebook creation, and collaboration with research professionals were acquired as valuable skills.

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