Development And Validation Of The Ramp Protocol (Rhythmic-Amplitude Motor Progression) For Improving Gait, Balance, And Functional Mobility In Individuals With Diabetic Peripheral Neuropathy: A Modified Delphi Study

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Background:

Diabetic Peripheral Neuropathy commonly leads to impaired gait, balance deficits, and reduced functional mobility, increasing the risk of falls and disability. Although various physiotherapy interventions exist, there is limited availability of structured amplitude- and rhythm-based rehabilitation protocols for this population.

Objective:

To develop and validate the Rhythmic-Amplitude Motor Progression (RAMP) protocol for improving gait, balance, endurance, and functional mobility in individuals with diabetic peripheral neuropathy.

Methods:

The RAMP protocol was developed based on literature review, clinical expertise, and principles derived from amplitude-based training such as LSVT BIG. The protocol was then validated using a modified Delphi method involving a panel of physiotherapy experts in neurorehabilitation. Experts evaluated the protocol components using a structured questionnaire across two Delphi rounds. Consensus was defined as ≥80% agreement.

Results:

After two rounds of Delphi evaluation, consensus was achieved for all components of the RAMP protocol including warm-up, amplitude-based movement training, rhythmic gait training, functional mobility exercises, and endurance training.

Conclusion:

The RAMP protocol was successfully developed and validated through expert consensus. This structured physiotherapy intervention may serve as a clinically applicable rehabilitation approach for improving gait and balance in individuals with diabetic peripheral neuropathy.

Keywords: Diabetic Peripheral Neuropathy, Rhythmic-Amplitude Motor Progression (RAMP), Gait Rehabilitation, Balance Training, Functional Mobility, Physiotherapy Intervention, Modified Delphi Method, Neurorehabilitation.

How To Cite This Article: Sanjyoth HS, Sathya P. Development and validation of the ramp protocol (rhythmic-amplitude motor progression) for improving gait, balance, and functional mobility in individuals with diabetic peripheral neuropathy: a modified delphi study. Int J Drug Deliv Technol. 2026;16(9s): 635-642; Doi: 10.25258/Ijddt.16.9s.67

Introduction

Diabetes mellitus is a major global health problem and is associated with several long-term complications affecting the nervous system and musculoskeletal function. One of the most common complications is Diabetic Peripheral Neuropathy (DPN), which affects nearly 30–50% of individuals with diabetes worldwide.[1] DPN results from metabolic and microvascular changes that cause progressive damage to peripheral nerves.[2] The condition is characterized by symptoms such as numbness, pain, paresthesia, and reduced proprioception, particularly in the distal lower extremities.[3] These sensory and motor impairments often lead to muscle weakness, impaired coordination, and reduced functional mobility in affected individuals.[4]

Gait and balance impairments are among the most significant functional consequences of diabetic peripheral neuropathy. Damage to peripheral sensory nerves reduces proprioceptive feedback and alters motor control, leading to abnormal gait patterns such as reduced gait velocity, shorter step length, and increased gait variability.[5] Individuals with DPN also demonstrate impaired postural stability due to deficits in somatosensory integration required for maintaining balance.[6] These impairments substantially increase the risk of falls and fall-related injuries among individuals with diabetes.[7] Studies have shown that decreased plantar sensation and lower-limb sensorimotor dysfunction significantly contribute to gait instability and balance deficits in this population.[8] Physiotherapy interventions play an essential role in the rehabilitation of individuals with diabetic

peripheral neuropathy by addressing deficits in balance, strength, and functional mobility. Exercise-based rehabilitation programs, including balance training, strengthening exercises, and gait retraining, have been reported to improve postural control and mobility in individuals with DPN.[9] Systematic reviews have demonstrated that structured exercise programs can significantly improve balance performance and reduce fall risk in individuals with diabetic neuropathy.[10] Despite these positive outcomes, rehabilitation approaches often vary widely across clinical settings, and there is a lack of standardized physiotherapy protocols specifically tailored for this population.[11]

Considering the complex sensorimotor impairments associated with diabetic peripheral neuropathy, there is a growing need for structured rehabilitation approaches that integrate multiple therapeutic strategies. Interventions incorporating movement amplitude training and rhythmic cueing have shown promising results in improving motor control and gait performance in neurological rehabilitation.[12] Programs such as LSVT BIG emphasize exaggerated movement amplitude and repetitive practice to enhance motor output and functional mobility.[13] However, similar structured protocols adapted specifically for individuals with diabetic peripheral neuropathy remain limited. Therefore, the present study aimed to develop and validate the Rhythmic-Amplitude Motor Progression (RAMP) protocol as a structured physiotherapy intervention to improve gait, balance, endurance, and functional mobility in individuals with diabetic peripheral neuropathy using a modified Delphi Method.

Methods

An initial literature search was conducted to identify existing evidence related to amplitude-based training, rhythmic cueing, gait rehabilitation, and balance interventions used in neurological and diabetic neuropathy populations. Relevant studies published in peer-reviewed journals were reviewed to understand commonly used therapeutic components, progression strategies, and safety considerations in rehabilitation programs.

Study Design

This study employed a methodological design to develop and validate a structured physiotherapy intervention protocol using a modified Delphi technique. The Delphi method is a systematic and iterative approach widely used in healthcare research to obtain consensus among experts through structured questionnaires and controlled feedback.[14] The study was conducted in accordance with the recommendations of the CREDES guideline, which provides standardized criteria for conducting and reporting Delphi studies in health research.[15] The Delphi process was used in the present study to achieve expert consensus regarding the content, structure, and clinical applicability of the Rhythmic-Amplitude Motor Progression (RAMP) protocol developed for individuals with diabetic peripheral neuropathy.

The initial draft of the RAMP protocol was developed following an extensive review of the literature related to gait rehabilitation, balance training, and physiotherapy interventions for individuals with diabetic peripheral neuropathy. Previous studies have demonstrated that exercise-based rehabilitation programs, including balance training and gait retraining, are effective in improving postural stability and functional mobility in individuals with diabetic neuropathy.[10]

The protocol design incorporated principles of amplitude-based movement training and rhythmic cueing strategies commonly used in neurorehabilitation programs such as LSVT BIG, which emphasize exaggerated movement amplitude to enhance motor performance and functional mobility.[13] Evidence suggests that amplitude-based motor training can improve gait performance and motor control in neurological rehabilitation settings.[16] Clinical expertise and established rehabilitation frameworks were also considered during the development of the protocol.

The preliminary protocol consisted of multiple components including warm-up exercises, amplitude-based movement training, rhythmic gait training, functional mobility activities, and endurance training. Each component was structured with clearly defined exercise descriptions, duration, and progression parameters. The preliminary protocol was subsequently converted into a structured questionnaire for evaluation by the expert panel during the Delphi process.

Expert Panel Selection

A panel of experts with experience in neurological physiotherapy and rehabilitation was recruited to participate in the Delphi study. Experts were selected using purposive sampling to ensure appropriate representation of both academic and clinical expertise relevant to the study topic.[17] Ethical approval for the study was obtained from the Institutional Ethics Committee of Dayananda Sagar University. All experts provided informed consent prior to participation.

The inclusion criteria for expert participation were:

The inclusion criteria for expert participation required individuals to have a minimum of five years of professional experience in physiotherapy practice or teaching, along with demonstrated

expertise in neurological rehabilitation, gait training, or balance rehabilitation. Additionally, experts were required to express their willingness to participate in multiple rounds of the Delphi process to ensure continuity and reliability in achieving consensus during the protocol validation.(Table 1)

Experts were invited through email communication and provided with detailed information regarding the study objectives and procedures. Participation was voluntary, and informed consent was obtained prior to the initiation of the Delphi rounds. Recruitment of experts with relevant experience is recommended in Delphi methodology to ensure credibility and reliability of the consensus process.[18]

Delphi Rounds

The modified Delphi process was conducted through iterative rounds to achieve expert consensus regarding the components of the RAMP protocol. A structured questionnaire describing the protocol components and exercise procedures was distributed electronically to the expert panel.

Round 1

During the first Delphi round, experts were asked to evaluate each component of the proposed protocol using a five-point Likert scale ranging from strongly disagree to strongly agree. The use of Likert scales in Delphi studies facilitates quantification of expert opinions and supports statistical evaluation of agreement levels.[17] Experts were also encouraged to provide comments and recommendations for modification of the protocol components. Responses were analyzed and summarized to identify areas of agreement and disagreement.

Round 2

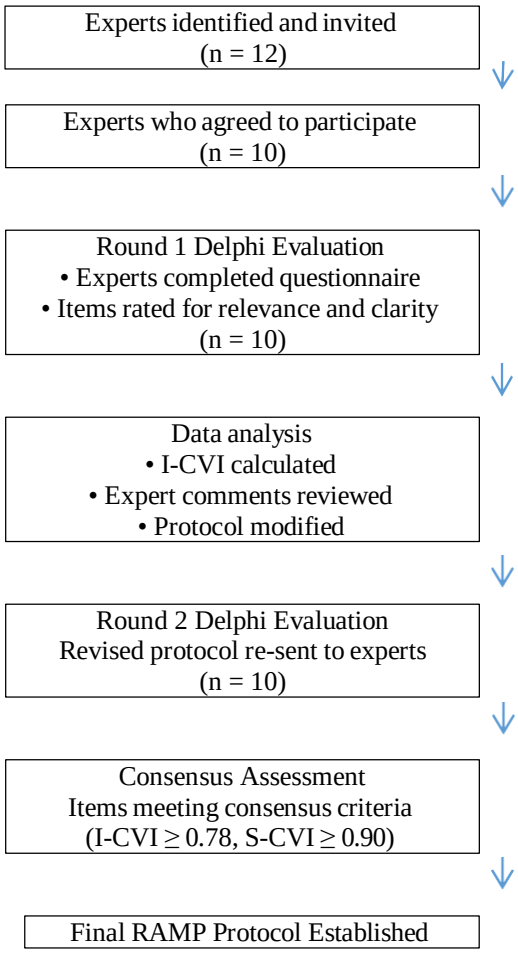
Based on feedback obtained in the first round, necessary modifications were made to the protocol components. The revised questionnaire was redistributed to the experts for further evaluation. Experts were provided with anonymized summaries of the responses obtained in the previous round to allow reconsideration of their responses. Iterative feedback and reassessment are key characteristics of the Delphi technique .that facilitate convergence toward consensus.[14]

Consensus Criteria

Consensus criteria were defined prior to conducting the Delphi study. Agreement was considered to be achieved when at least 80% of experts rated a protocol component as “agree” or “strongly agree” on the Likert scale, which is a commonly used threshold in healthcare Delphi studies.[7] Items that did not meet the predefined consensus threshold were reviewed and modified according to expert feedback and included in the subsequent Delphi round for re-evaluation.

The Delphi process continued until consensus was achieved for all components of the RAMP protocol. The final protocol represented the collective agreement of the expert panel regarding a structured physiotherapy intervention aimed at improving gait, balance, endurance, and functional mobility in individuals with diabetic peripheral neuropathy.

Figure 1. Flow diagram illustrating the modified Delphi process used for the development and validation of the RAMP protocol



Results

Content Validity of the RAMP Protocol

Content validity of the RAMP protocol questionnaire was evaluated by 10 subject experts using a 4-point Likert scale ranging from 1 (not relevant) to 4 (highly relevant). Ratings of 3 or 4 were considered relevant, while ratings of 1 or 2 were considered not relevant for the calculation of the Content Validity Index (CVI). The Item-Level Content Validity Index (I-CVI) was calculated for each item, and the Scale-Level Content Validity Index using the average method (S-CVI/Ave) was computed to determine overall content validity.[21]

For a panel of ten experts, an I-CVI value ≥ 0.78 is considered acceptable.[20] All eight items included in the RAMP protocol met this criterion. The I-CVI values ranged from 0.80 to 1.00, indicating strong agreement among the experts regarding the relevance and clarity of the protocol components.Minor suggestions were provided by experts for items related to rhythmic gait training and endurance training. However, these items did not require removal and were retained after minor wording clarification.

The scale-level content validity index (S-CVI/Ave) was 0.95, demonstrating excellent overall content validity of the RAMP protocol.(Table 2)

To account for agreement occurring by chance, modified kappa statistics were calculated. The kappa values ranged from 0.70 to 0.91, indicating good to excellent agreement among experts beyond chance.[21] These findings confirm that the RAMP protocol demonstrates strong content validity and expert consensus. (Table 3)

Final RAMP Protocol

The final RAMP protocol was described according to the TIDieR Checklist, which provides a structured framework for reporting rehabilitation interventions to ensure reproducibility.

Intervention Name:Rhythmic–Amplitude Motor Progression (RAMP) Protocol

Conceptual Framework: The RAMP protocol is grounded in principles of auditory–motor entrainment, amplitude scaling, and task-specific motor learning aimed at improving gait adaptability and functional mobility in individuals with Diabetic Peripheral Neuropathy. These principles are commonly used in neurological rehabilitation to enhance motor coordination and movement efficiency.[12]

Intervention Dosage and Structure

The RAMP intervention program will be conducted over a total duration of six weeks, with participants attending three sessions per week. Each session lasted approximately 40–45 minutes and will be administered under the supervision of a physiotherapist experienced in neurorehabilitation to ensure proper execution of exercises, safety, and appropriate progression of the training protocol.

Entry Criteria

Participants will be included only if they are medically stable and able to ambulate independently or with assistive devices. Individuals will be required to obtain medical clearance for participation in moderate-intensity physiotherapy and demonstrate the ability to follow verbal instructions necessary for gait and balance training.

Progression Criteria

Progression to subsequent phases of the RAMP protocol occurred only when participants is able to successfully complete the tasks of the current phase while meeting specific clinical criteria. These included maintaining pain intensity ≤3/10 on the Numerical Pain Rating Scale, experiencing no episodes of loss of balance requiring therapist assistance, demonstrating stable blood glucose levels without symptoms of hypoglycemia or hyperglycemia, and performing movements with adequate quality, including appropriate amplitude and postural alignment. Decisions regarding progression will be made based on clinical judgment, consistency of task performance, and the participant's tolerance to the intervention, ensuring both safety and effective rehabilitation progression.

Safety / Regression Criteria

Training intensity or task complexity will be reduced when participants exhibits the signs indicating reduced tolerance to the intervention. These signs includes increased neuropathic symptoms such as foot pain or numbness, excessive fatigue or dizziness, difficulty synchronizing movements with auditory cues, or a decline in movement quality and postural control during task performance. When such responses observed, the exercise intensity or task difficulty will be appropriately modified to ensure participant comfort and safety. These predefined safety and regression criteria will be incorporated into the protocol to enhance clinical reproducibility, ensure participant safety, and maintain the quality of intervention delivery.

Intervention Phases

Week 1–2: Familiarization Phase

Goal: Development of movement awareness and rhythmic entrainment.

Key components includes: Large-amplitude stepping movements, Postural alignment training and Basic rhythmic gait practice using metronome cues.

Week 3–4: Progression Phase

Goal: Improvement of dynamic balance and gait control.

Exercises includes: Multidirectional stepping, Rhythmic gait training with increased complexity and Functional mobility tasks such as turning and obstacle negotiation.

Week 5–6: Integration and Endurance Phase

Goal: Promote automaticity of movement and improve endurance.

Training emphasizes: Continuous walking practice, Dual-task activities and Functional gait tasks simulating real-world mobility demands

Cognitive Strategies

Cognitive movement strategies will be incorporated throughout all phases of the intervention to enhance motor learning and

movement control. These strategies included verbal self-instruction, where participants will be encouraged to use cues such as "big step" and "tall posture" to facilitate larger and more controlled movements. Participants are also guided to maintain an internal focus on posture and movement amplitude to improve body awareness. In addition, external cueing using a metronome and visual markers will be employed to support rhythmic movement and gait coordination. Mental rehearsal prior to selected tasks is also encouraged to promote better motor planning and execution during functional activities.

Rhythmic Cueing

A metronome will be used as an auditory cue to facilitate temporal consistency and step timing. Rhythmic auditory cueing has been shown to improve gait rhythm and coordination in neurological rehabilitation settings.[22]

Table 2: Content Validity Index (CVI) of the RAMP Protocol Components

Item	Description (Short)	Experts rating 3–4	I-CVI	Interpretation
1	Overall relevance	10 / 10	**1.00**	Excellent
2	Scientific rationale	10 / 10	**1.00**	Excellent
3	Session duration & frequency	8 / 10	**0.80**	Acceptable
4	Suitability of exercises	10 / 10	**1.00**	Excellent
5	Safety of protocol	8 / 10	**0.80**	Acceptable
6	Feasibility	10 / 10	**1.00**	Excellent
7	Clarity of description	10 / 10	**1.00**	Excellent
8	Logical sequencing	10 / 10	**1.00**	Excellent

Scale-Level Content Validity Index (S-CVI)

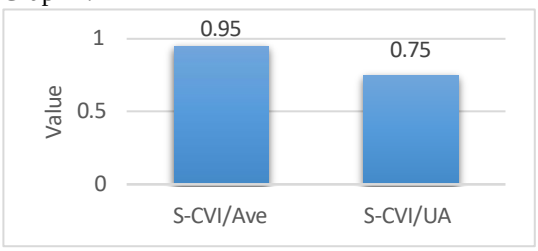
S-CVI/Ave

S-CVI/Ave=7.6/8= 0.95 =0.95

S-CVI/Ave	Meaning
≥ 0.90	Excellent content validity

With 10 experts, an I-CVI ≥ 0.78 is considered acceptable.All items meet acceptability criteria.Items 3 and 5 may benefit from minor wording or procedural clarification, but do not need deletion.

Graph 1.



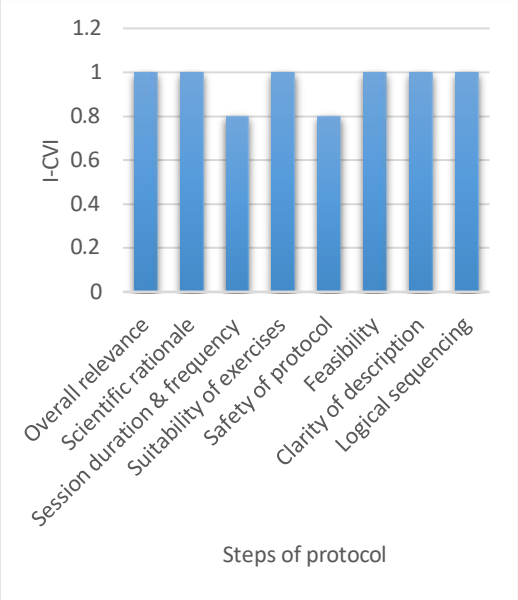
Content validity of the RAMP protocol questionnaire was evaluated by ten subject experts using a four-point Likert scale ranging from 1 (not relevant) to 4 (highly relevant). Item-level content validity indices (I-CVI) were calculated by dichotomizing responses into relevant (ratings 3 or 4) and not relevant (ratings 1 or 2). The scale-level content validity index was computed using the average method (S-CVI/Ave). The item-level content validity index ranged from 0.80 to 1.00. The scale-level content validity index (S-CVI/Ave) was 0.95, indicating excellent content validity of the RAMP protocol. All items met the recommended acceptability threshold.

Table 3. Content Validity Indices and Modified Kappa for RAMP Protocol

Item	Description	Experts (3–4)	I-CVI	Pc	Modified Kappa (K*)	Interpretation
1	Overall relevance	10/10	1.00	0.001	**1.00**	Excellent
2	Scientific rationale	10/10	1.00	0.001	**1.00**	Excellent
3	Session duration & frequency	8/10	0.80	0.044	**0.79**	Good–Excellent
4	Suitability of exercises	10/10	1.00	0.001	**1.00**	Excellent
5	Safety of protocol	8/10	0.80	0.044	**0.79**	Good–Excellent
6	Feasibility	10/10	1.00	0.001	**1.00**	Excellent
7	Clarity of description	10/10	1.00	0.001	**1.00**	Excellent

8	Logical sequencing	10/10	1.00	0.001	**1.00**	Excellent

Graph 2.



The modified kappa statistics demonstrated excellent agreement beyond chance for most items (K* = 1.00), while two items showed good-to-excellent agreement (K* = 0.79), supporting strong content validity of the instrument.

Content validity of the instrument was evaluated by ten subject experts using a 4-point relevance scale. Item-level content validity indices (I-CVI) ranged from 0.80 to 1.00. Six items achieved universal agreement among experts (I-CVI = 1.00), while two items demonstrated acceptable agreement (I-CVI = 0.80). Modified kappa statistics indicated excellent agreement beyond chance for most items (K* = 1.00) and good-to-excellent agreement for two items (K* = 0.79). The scale-level content validity index was high, with S-CVI/Ave = 0.95 and S-CVI/UA = 0.75, confirming strong overall content validity of the instrument.

Discussion

The present study aimed to develop and validate a structured physiotherapy intervention protocol for individuals with diabetic peripheral neuropathy using expert consensus through the modified Delphi method. The findings demonstrated that the RAMP protocol achieved strong agreement among experts, confirming its relevance and applicability for clinical rehabilitation.

Gait and balance impairments are common complications of Diabetic Peripheral Neuropathy, resulting from sensory loss, reduced proprioception, and impaired neuromuscular control.[2] These impairments contribute to slower walking speed, altered gait patterns, and an increased risk of falls. Exercise-based rehabilitation programs have been shown to improve postural stability, gait performance, and functional mobility in individuals with diabetic neuropathy.[11] However, many existing interventions lack a clearly defined structure or progression framework.

The RAMP protocol was therefore designed to integrate evidence-based principles including amplitude-based movement training, rhythmic cueing, and task-specific functional training. Amplitude-oriented training has been reported to enhance motor activation and movement scaling by encouraging exaggerated movement patterns and repetitive practice.[28] Similarly, rhythmic auditory cueing improves gait timing and coordination by facilitating auditory–motor synchronization.[24]

Another strength of the RAMP protocol is the incorporation of cognitive movement strategies, which promote motor learning and movement automaticity. These strategies may help individuals with diabetic neuropathy improve motor planning and adaptability during functional activities.

The use of the Delphi method allowed systematic integration of expert knowledge during protocol development. Consensus-based approaches are widely used for developing clinical guidelines and intervention frameworks when empirical evidence is limited.[14]

Conclusion

The present study successfully developed and validated the Rhythmic–Amplitude Motor Progression (RAMP) protocol as a structured physiotherapy intervention for individuals with diabetic peripheral neuropathy. Content validity analysis demonstrated excellent agreement among experts, confirming the relevance and clarity of the protocol components.

The RAMP protocol integrates amplitude-based training, rhythmic gait cueing, functional mobility exercises, and cognitive movement strategies to address key impairments affecting gait and balance in individuals with diabetic peripheral neuropathy.This validated protocol provides a standardized and clinically applicable rehabilitation framework that may be implemented in physiotherapy practice to improve gait performance, balance stability, and functional mobility.

Although the RAMP protocol demonstrated strong content validity through expert consensus, the study has certain limitations. The protocol was validated using a modified Delphi process rather than clinical testing in patients with

diabetic peripheral neuropathy, and the number of experts included in the panel was relatively small. Therefore, future studies should evaluate the clinical effectiveness of the RAMP protocol through randomized controlled trials to determine its impact on functional outcomes such as gait, balance, and mobility in individuals with diabetic peripheral neuropathy. Additionally, studies involving larger sample sizes and longer follow-up periods are required to examine the sustainability of treatment effects. Future research may also explore the underlying neurophysiological mechanisms of rhythmic and amplitude-based training in improving sensorimotor control. Comparative studies assessing the effectiveness of the RAMP protocol against other established physiotherapy interventions could further strengthen evidence of its clinical value. Moreover, incorporating objective assessment tools such as wearable sensors and motion analysis systems may enhance the precision of gait and balance measurements. Finally, future work should investigate the feasibility of integrating cognitive movement strategies and technology-assisted rehabilitation approaches to optimize functional outcomes in individuals with diabetic peripheral neuropathy.

The authors declare that there are no conflicts of interest regarding the publication of this paper. The study received no external funding, and the authors report no financial or personal relationships that could have influenced the work reported in this manuscript.

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