



Clinical Trial Details (PDF Generation Date :- Sat, 03 Jun 2023 09:57:53 GMT)

CTRI Number	CTRI/2020/04/024792 [Registered on: 22/04/2020] - Trial Registered Prospectively	
Last Modified On	24/06/2022	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Behavioral	
Study Design	Single Arm Study	
Public Title of Study	"Integrating the palliative care and symptom relief into Primary Health Care"	
Scientific Title of Study	Effectiveness of Capacity Building: Integrating the palliative care and symptom relief into Primary Health Care - An Evaluative approach	
Secondary IDs if Any	Secondary ID	Identifier
	NIL	NIL
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator	
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Source of Monetary or Material Support	Source of Monetary or Material Support			
	> ICMR - ICRC Manipal College of Nursing Manipal Academy of Higher Education Manipal Karnataka State India			
Primary Sponsor	Primary Sponsor Details			
	Name	Dr Malathi G Nayak		
	Address	Associate Professor Community Health Nursing Department Manipal College of Nursing MAHE Manipal.		
	Type of Sponsor	Government funding agency		
Details of Secondary Sponsor	Name	Address		
	Dr Baby S Nayak	Professor & Head Manipal College of Nursing MAHE Manipal		
	Dr Naveen Salins	Professor & Head, Department of Palliative Medicine and Supportive Care, Kasturba Medical College & Hospital, MAHE, Manipal		
	Ms Radhika R Pai	Assistant Professor, Manipal College of Nursing, MAHE, Manipal.		
Countries of Recruitment	List of Countries			
	India			
Sites of Study	Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
	Dr Malathi G Nayak	Manipal College of Nursing Manipal	Associate Professor Department of Community Health Nursing Manipal College of Nursing, Manipal Academy Higher Education Madhav Nagar. Udupi KARNATAKA	09449586431 malathi.nayak@manipal.edu
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Kasturba Medical College and Kasturba Hospital	Approved	23/03/2020	No
Regulatory Clearance Status from DCGI	Status		Date	
	Not Applicable		No Date Specified	
Health Condition / Problems Studied	Health Type		Condition	
	Healthy Human Volunteers		Enhancement of the capacity of the primary health care workers in need assessment and symptom management of cancer patients with regard to palliative care	
Intervention / Comparator Agent	Type	Name	Details	
	Intervention	Capacity building programme	The palliative care module will be prepared and training will be provided to the Primary Health Care Workers (Staff nurses, ANMs, ASHA workers) to provide effective palliative care services for cancer patients.	



		Workshop of 1 day will be planned for ASHA workers and 3 days for staff nurses/ANMs.
Comparator Agent	Not applicable	Not applicable
Inclusion Criteria	Inclusion Criteria	
Age From	20.00 Year(s)	
Age To	55.00 Year(s)	
Gender	Both	
Details	Primary Health care workers (Staff nurses, Auxiliary Nurse Midwives & ASHA workers) those who are: 1. Working in PHC/SCs of Udupi District. 2. Willing to participate in the study 3. Able to provide palliative care for children and adults with cancer	
Exclusion Criteria	Exclusion Criteria	
Details	Primary Health care workers (Staff nurses, Auxiliary Nurse Midwives & ASHA workers) those who are not willing to participate.	
Method of Generating Random Sequence	Not Applicable	
Method of Concealment	Not Applicable	
Blinding/Masking	Not Applicable	
Primary Outcome	Outcome	Timepoints
	1. Improvement in knowledge, skill and change in attitude of PHCWs after palliative care training. 2. Improvement in palliative care need identification using palliative care mobile app	Three years
Secondary Outcome	Outcome	Timepoints
	Identifying facilitators and barriers for palliative care delivery in rural and remote geographical areas.	2 years and 6 months
Target Sample Size	Total Sample Size=1440 Sample Size from India=1440 Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials	
Phase of Trial	N/A	
Date of First Enrollment (India)	01/09/2020	
Date of First Enrollment (Global)	No Date Specified	
Estimated Duration of Trial	Years=3 Months=0 Days=0	
Recruitment Status of Trial (Global)	Not Applicable	
Recruitment Status of Trial (India)	Open to Recruitment	
Publication Details	Nil	
Brief Summary	This study is aimed to determine the effectiveness of capacity building program on palliative care in enhancing the capacity of the Primary Health Care Workers (PHCWs) in need assessment and symptom management	



of cancer patients. A quasi experimental study will be conducted using evaluative approach among PHCWs (staff nurses, ANMs and ASHA workers) through training program and implementation of mobile app for palliative care of cancer patients. The proposed study will be implemented among 1440 PHCWs in three taluks of Udupi District, Karnataka State, India. PHCWs after the training are expected to demonstrate gain in knowledge & skill and change in attitude in providing palliative care for cancer patients by identifying and implementing palliative care services by using mobile app.