



TACT NEWSLETTER
Special Edition

July 2004

TACT Leaders

Message from the TACT Clinical Coordinating Center

Since our last newsletter, there has been a surge of randomizations. Several new sites have joined us, and we would like to take this opportunity to welcome all of all the newcomers.

There are currently 281 randomized patients and we are moving toward our goal of 2372 patients.

In order to be successful, patient recruitment is the key. This newsletter features interviews with the current randomization leader, Dr. Rajiv Chandra and also with Dr. Harmony Reynolds, a current TACT Site Investigator. In addition, there are recruitment tips on pages 5&6.

We wish you well in your endeavor. Through teamwork, we will succeed. We are always here to help. Please call the CCC anytime with questions or issues you have.

Let's work together to meet and exceed our enrollment goals!

<u>Site</u>	<u>Investigator/Coordinator</u>	<u>Patients</u>
234	Rajiv Chandra	33
227	Sangeeta Shah/ Tracey Wilks	21
220	Steven Burkholz/ Dolly Corbin	19
312	Tammy Born/ Judy Schneider	14
239	Randy Hartman/Lynn King/Amy Heineman	14
406	Patrick Golden/ Kathy Sasser	13
113	Russell Silverman/ Sherri Loucks	12
115	Robert Weiss/ Diane Cass	10
212	Joseph O'Bryan/ Mary Barr	9
232	John Griffin/ Terry Mellinger	7
112	Reed Snider/ Jean Provencher	7
326	Kenneth Ganapini/ Venus Barney	7
302	Greg Flaker/ Jamie Easley	7
131	Terry Chappell/Marcia Arnold	7
407	Nampalli Vijay/ Melinda Washam	6
249	Connie Ross/Michelle Simpson	6
223	Roy Heilbron/ Celia Heilbron	6
238	Lawrence Miller/Deanna Overbeck	6
228	James Carter/David Maddox**	6
217	James Carter/ David Maddox**	5
216	Ricky Schneider/ Amy Abreu	4
107	Allan Magaziner/ Betty Ann Persico	4
132	Ralph Miranda/Barbara Cassella	3
247	Pieter de Wet/Cynthia de Wet	3
242	Miguel Trevino/ Tracy Osborn	3
120	Majid Ail/ Boobullah Baig	3
110	Pamela Ouyang/ Melanie Herr	3
215	Shalendra Varma/ Sharon Collins	3
221	Robert Cicia-McLean/Pablo Guala	3
125	Michael Schachter/ Sally Minniefield	3
**PI and Coodinator for 2 or more sites		
Total		281



***** SUMMIT AWARD *****

Congratulations to site 234, Dr. Rajiv Chandra, Terry Murphy, Michelle Pacetti and Jayne Pauley who have randomized 33 patients.



TACT SPOTLIGHT INTERVIEW



This month's TACT spotlight interview is with Dr. Rajiv Chandra from Melbourne, Florida. Dr. Chandra and his staff (Michelle, Terry and Jayne) have randomized **33** patients since the Investigator's Meeting in March. Dr. Chandra is a cardiologist who also practices alternative and complementary medicine

From left to right: Michelle Pacetti, LPN, Terry Murphy, Rajiv Chandra, MD (Site Investigator), Jayne Pauley, RN

Why have you had so much success in recruiting patients?

We are a working team at site 234 in Melbourne. I am the Principal Investigator who oversees the screening and randomization process, Terry Ann Murphy is the Study Coordinator, LPN Michelle Pacetti assists in completing patient medical history, screening and verification of MI (which is the most difficult part of the process when patients are referred to us) as well as handling infusions and RN Jayne Pauley is our Certified Chelation Therapist handling infusions. Our team is based on the following: experience – years of clinical research, teamwork, organization and efficiency.

How did you advertise for this trial? What venues did you contact?

I have a large practice in a county that has a long history of chelation (Dr. Rogers, an originator of chelation practiced here). We have a marketing program in place based around my own weekly radio show "Straight Up With Dr. Chandra," and newspaper ads, which are great recruiting tools. I have been an active member of the community since 1986 and am well known here.

Examples of some of the additional marketing tools we use include inexpensive advertisements such as a large poster in our lobby (a copy of the approved TACT ad \$38), flyers (8 ½ x 11), and copies of the TACT ad for our patients to take home or give to friends/family. These were very cheap to produce 1,000 (about \$30). We enclosed these flyers in our monthly statements so there is no additional postage involved, just the small cost of photocopies. There is a laminated large copy of the TACT ad in each and every one of our exam rooms (costs \$6.00 each). I also sponsor local events for the seniors in our community and TACT information is made available at each event.

How important do you feel this trial is?

Everyone at site 234 feels the success of this trial is extremely important. I am a cardiologist that integrates CAM into my practice. This trial should once and for all prove or disprove the benefits of chelation therapy and we are very excited to be a part of this historic trial.

How many patients do you project to enroll?

Site 234 hopes to enroll **100** patients. With our chelation center and our cardiac monitoring room, we are currently set up to handle 35 per week. Our facility is in the process of expanding and we will be able to accommodate more participants for infusions in 2005.

It is important to maintain a schedule that is convenient for the patients and we always make sure to thank them and tell them how much we appreciate their time commitment and enthusiasm. Each and every one of them are important and their participation can actually change the course of future medical treatment and ensure the success of TACT.



The following article about Dr. Harmony Reynolds appeared on CBS Newspath in April. Since then, this story was broadcasted by several local CBS affiliates throughout the country which resulted in numerous calls to the Clearinghouse.

Credit: Dr. Mallika Marshall, CBS News

Last summer, Richard Chartoff was going through a tough recovery after a heart attack and double bypass surgery. It took three months of rehabilitation before he could return to his everyday activities. Chartoff says, "It was like getting hit with a train. It was an experience I wouldn't recommend to anyone."

Doctors are trying to find out if an "alternative" treatment can help stop blockages in heart patients. It's called chelation, and is already being used by thousands of Americans, even though it's not government approved and most insurers don't cover it.

Dr. Harmony Reynolds, cardiologist, NYU Medical Center said, "Chelation therapy is being used by 60,000 patients a year at a cost of tens of millions of dollars per year, just for the treatment of heart disease and we're not sure that it works."

Chelation therapy is a synthetic amino acid that acts like a sponge, removing certain metals, minerals and calcium from the blood. One of several theories is removing these items keeps them from building up as plaque in the heart. But before researchers can address why chelation works this study will find out if it actually works at all.

Dr. Reynolds, says, "This is unlike usual drug development where we find out why a drug may work and then we test it. Here, it's being used already. We need to prove it's effective and then figure out why it works." The study will take about five years to complete and will involve over 2300 patients around the nation.

As one of the study participants Richard doesn't know if he's actually receiving chelation or just a placebo. Richard Chartoff, says, "All I can say is, I'm glad to be alive and glad to be part of this study." And he hopes that even if the therapy doesn't help him, it may help someone else, someday.



REMINDER

Before submitting **ANY** advertisements or press releases, please make sure to send a copy to the TACT CCC for review. Upon review at the CCC, we will determine if IRB approval is needed. In addition, please notify the CCC of any future television or radio interviews one week prior to their occurrence.

PATIENT RECRUITMENT TIPS

Finding Patients

Enroll, enroll, enroll. We know we need to reach our enrollment targets for TACT to succeed. But where do we start?

Barriers to Enrollment

First, think about why someone would *not* participate. Why start with the negative? Because we need to understand the challenges in order to find solutions.

- Time commitment required for the study
- Unwillingness to be randomized
- Primary care physicians don't refer

Motivating Factors

So, why would someone be interested? You can appeal to these factors that we have heard as reasons for participating.

- Altruism; wanting to contribute to research
- Hopes that studying this therapy may show that chelation may prevent another heart attack
- Desire for close medical monitoring

Reaching Patients

Now that we understand a little more about some of the recruitment challenges, we can determine the best ways to reach patients. Don't forget that people often need to hear a message repeated several times before they will take action. So, plan to undertake a variety of activities.

- *Your practice*: Do you see patients who may be eligible for this study? Put a flyer in the waiting room and exam rooms to let people know about the study, and don't forget to talk about the study with your patients.
- *Word-of-mouth*: Do you have current patients enrolled in the study? Provide them with materials (such as brochures or flyers) so they can talk to their friends and family about participating
- *Advertising*: You can either purchase ads or look for opportunities for free advertising. Many community papers have an announcements section and may include calls for study volunteers.
- *"Earned" media*: This is different from advertising. This is when a newspaper, local TV news, or radio station reports on the study. It is helpful to send a press release to local reporters and news editors, and be sure to follow up with a phone call.
- *Community outreach*: Contact local community organizations and ask if they will allow you to give a presentation to their members or put an article in their newsletter.



Reaching Referring Physicians

Don't forget to reach out to your colleagues who may have eligible patients. You can do this in a variety of ways:

- Letters to cardiologists in your area (following up with a phone call is highly recommended)
- Present grand rounds at area hospitals (the TACT CCC will provide PowerPoint slides)
- Arrange one-on-one or small group meetings

Don't forget! As you conduct outreach, be sure to include a telephone number or Web address for people to get more information. The NCCAM Clearinghouse is equipped to field calls, conduct an initial prescreen, and refer patients to the most convenient site.

- Toll-free number: **1-888-644-6226**.
- Study Web site: **<http://nccam.nih.gov/chelation>**.

Patient Recruitment Toolkit

Sites should have received a patient recruitment toolkit in a 3-ring binder (those at the investigator meeting in March already received their toolkits). This toolkit provides practical ideas, tips, and instructions for conducting various types of outreach. As promised, brochures, flyers, customizable news releases, and ads are also being produced and will be sent to you shortly.

If you have any questions or want to discuss any ideas, please contact Alyssa Cotler in the NCCAM Office of Communications. She can be reached at 301-451-3851 or cotlera2@mail.nih.gov.

TACT Communication

TACT (DCRI) Helpline 800-545-3853

Mt. Sinai 305-674-2794

DCRI 919-668-8253



TOGETHER, WE CAN
SUCCEED!!!!!!!!!!!!!!

CLINICAL SITES NEEDED !!!!!

If you know physicians that would be interested in participating as a clinical site in TACT, please have them contact Jewmaull Reed at (305) 674 - 2298 or at jreed@msmc.com for more information.